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(54) **METHODS AND DEVICES FOR TREATING A SYNDESMOSIS INJURY**

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USPC ..... 606/300–321; 623/13.13–13.16
See application file for complete search history.

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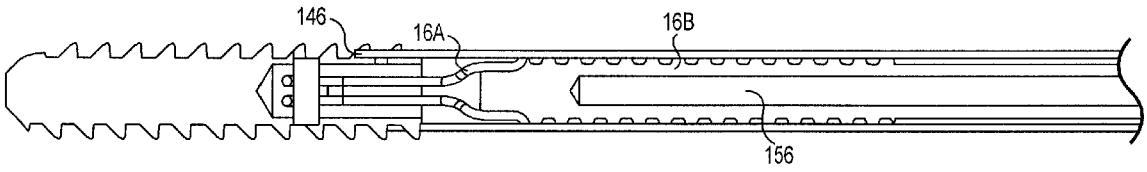
(57) **ABSTRACT**

Embodiments relate to implantable devices for the treatment of syndesmosis injuries. Embodiments include a first anchor attachable to a first bone, the first anchor being coupled to a flexible component, the flexible component in turn being coupled to a base component. The base component may be rigid, and may be externally threaded for engaging with a second anchor. Position of the second anchor may be adjusted by rotating the second anchor with respect to the base component, thereby adjusting relative position of the two bones. An assembly may be created in which an outer tube contains the flexible component and the base component inside the outer tube, and at its distal end the outer tube may engage the first anchor so as to allow transmission of torque. The outer tube may be withdrawn proximally after implantation of the first anchor. The bones may be a tibia and a fibula.

**24 Claims, 31 Drawing Sheets**



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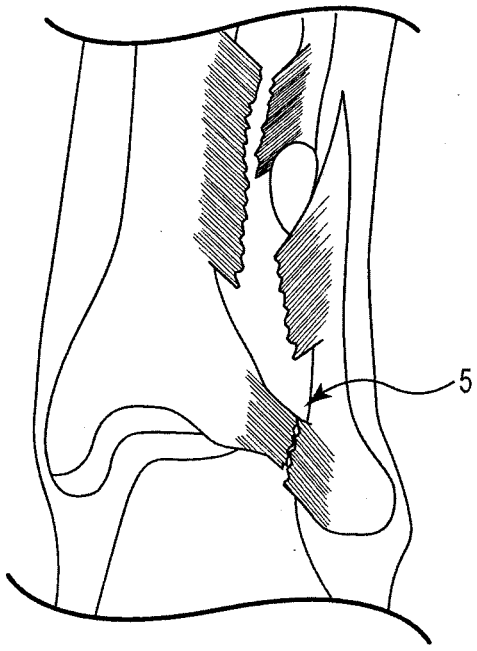


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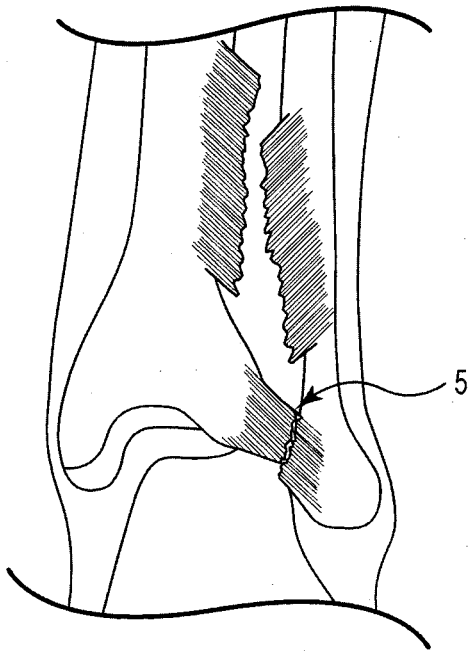


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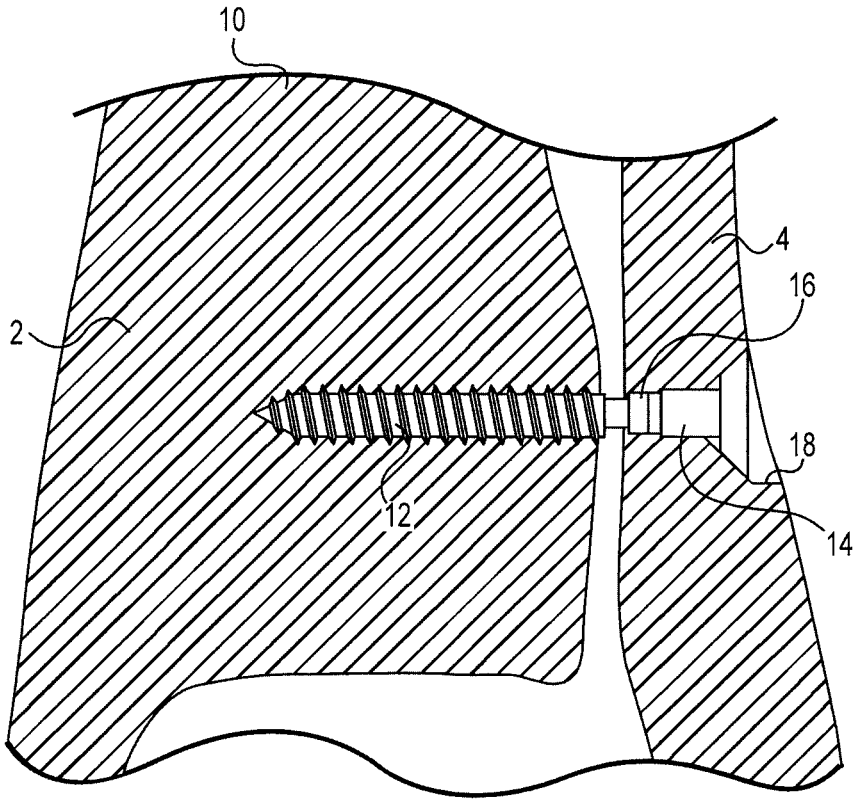


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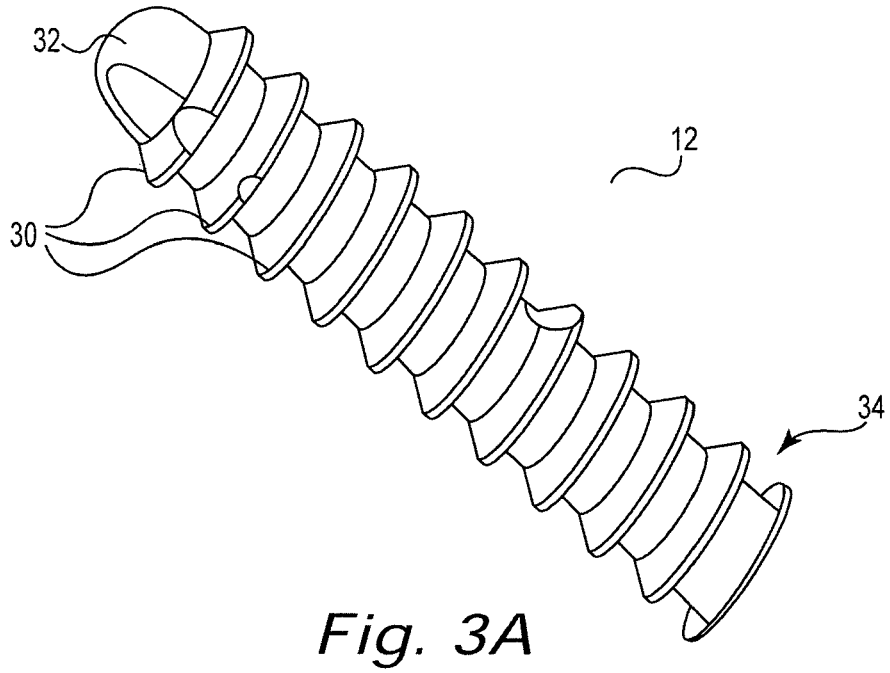


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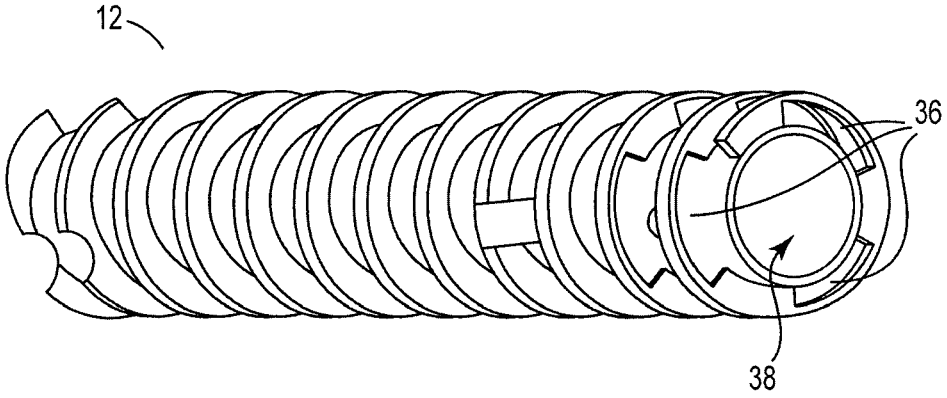


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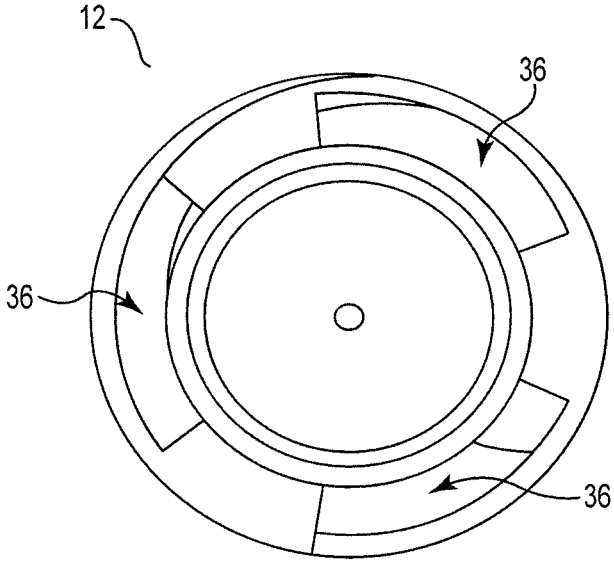
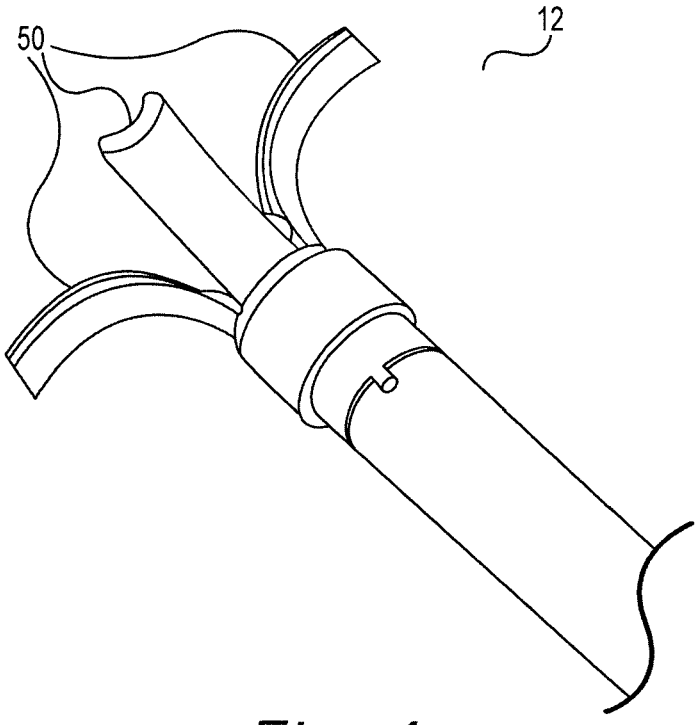



Fig. 3C

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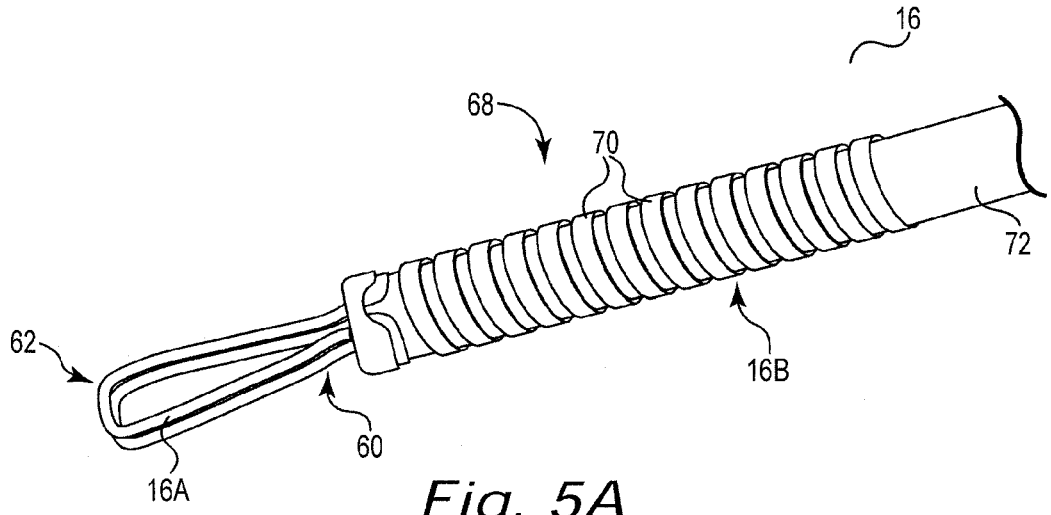


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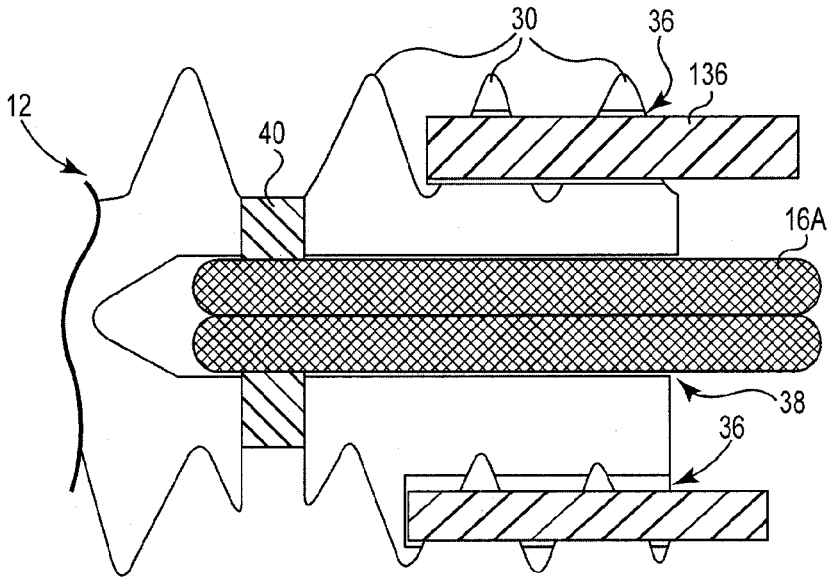


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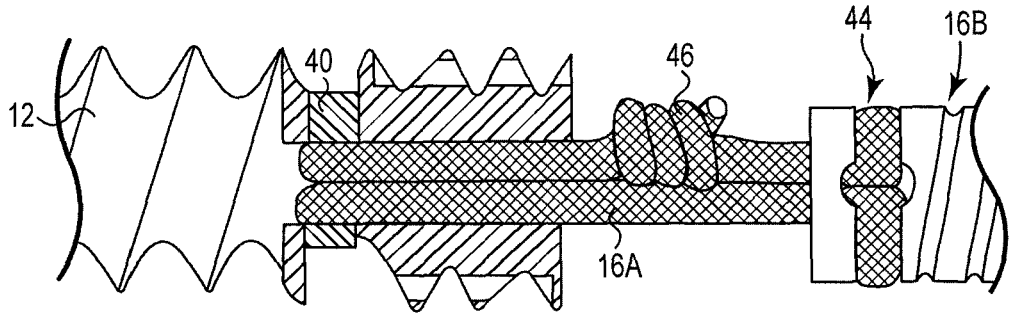


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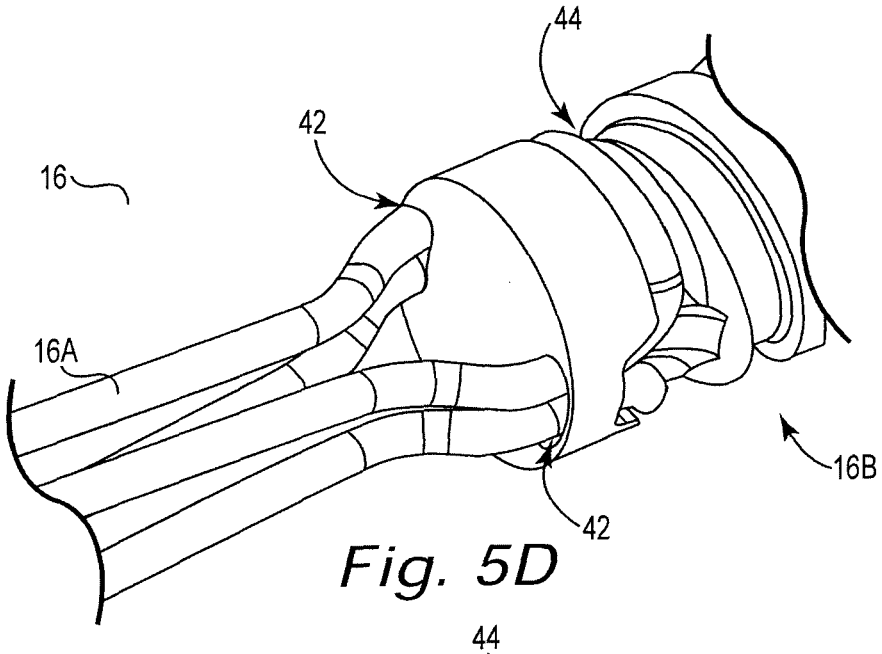
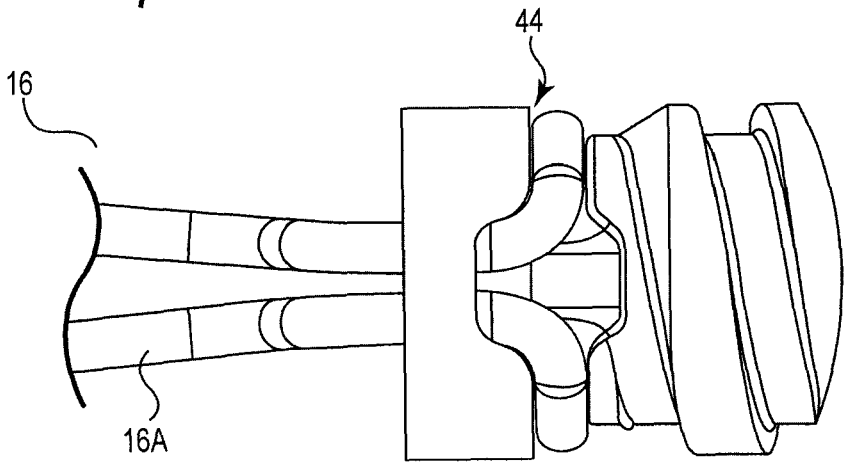



Fig. 5D

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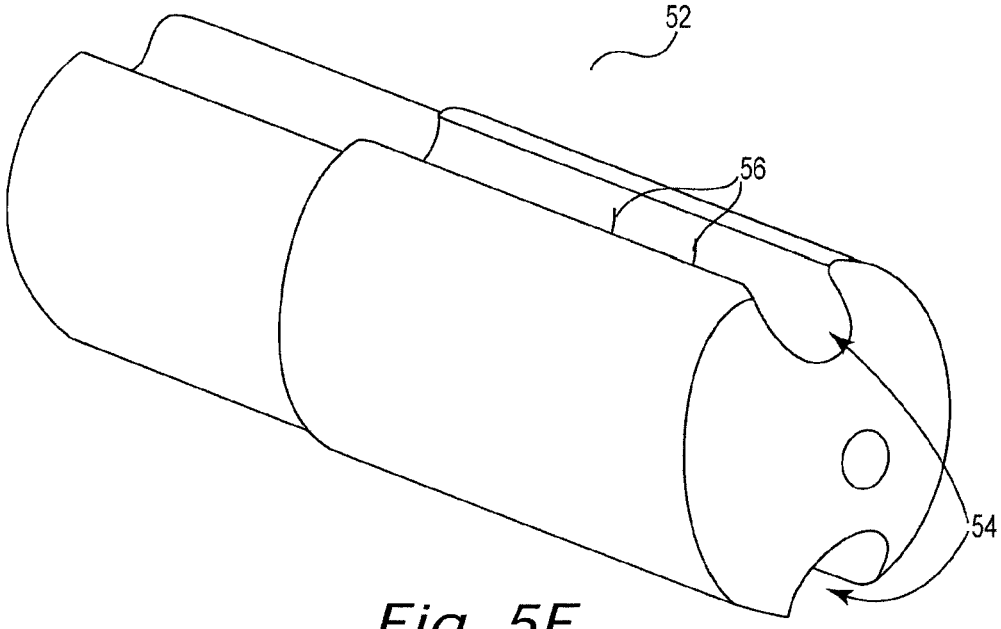


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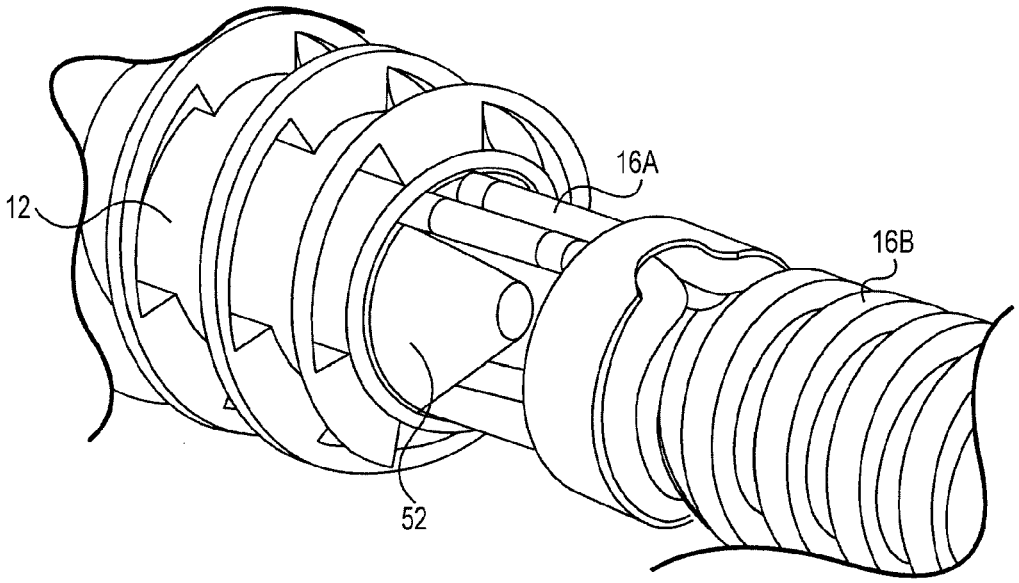


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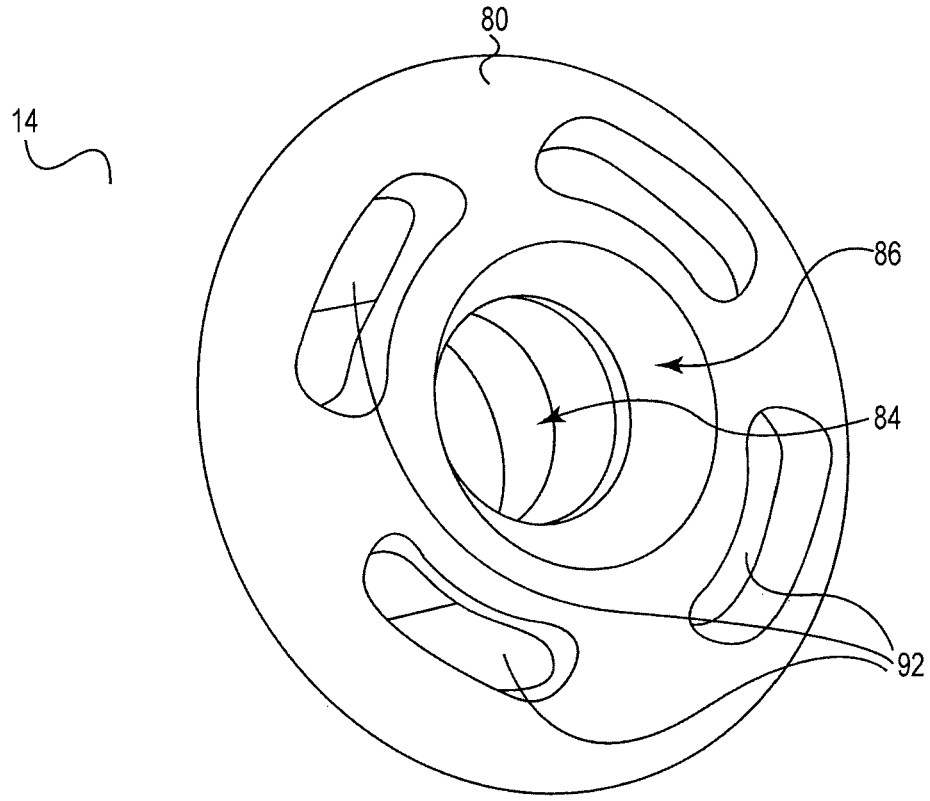


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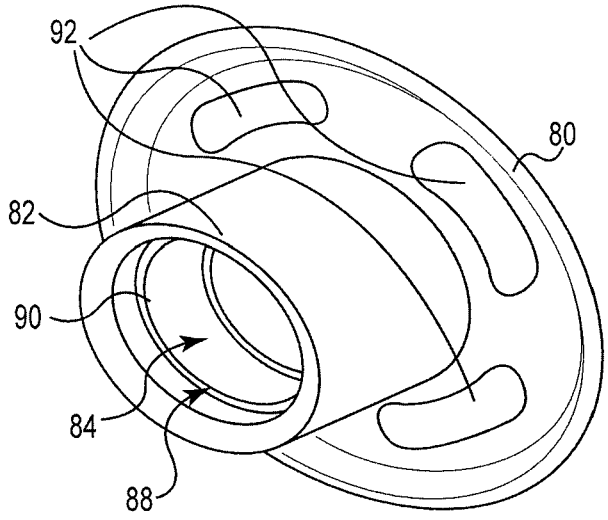


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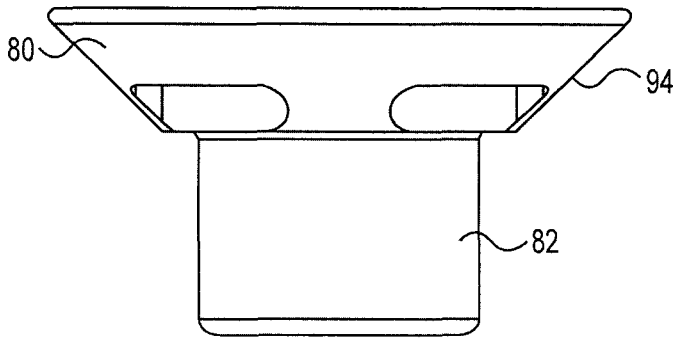


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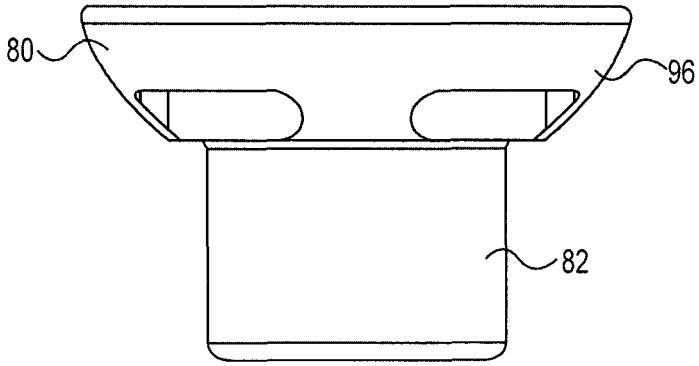


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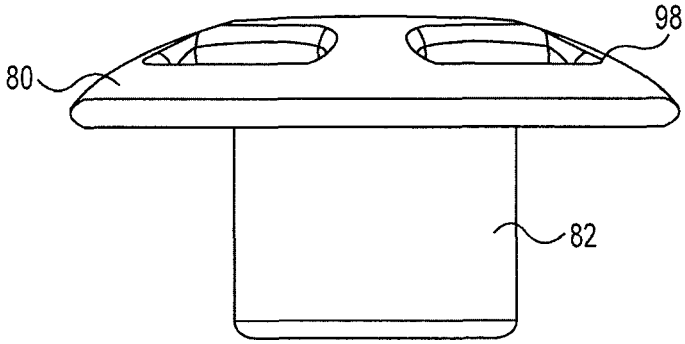


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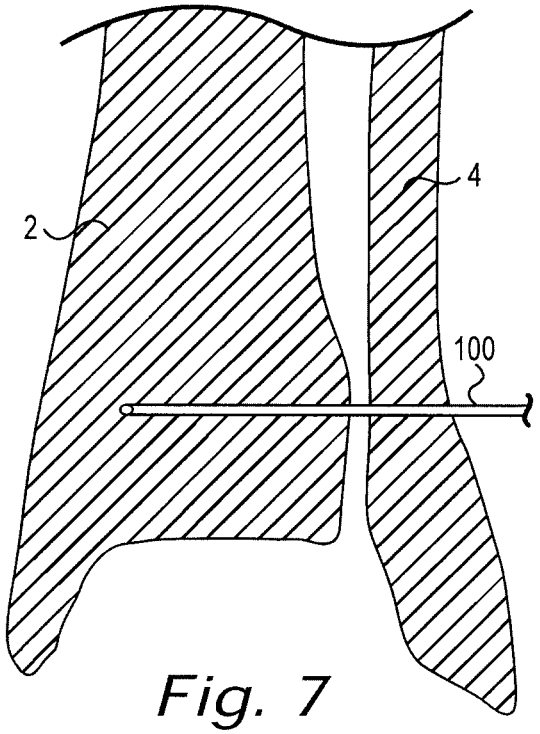


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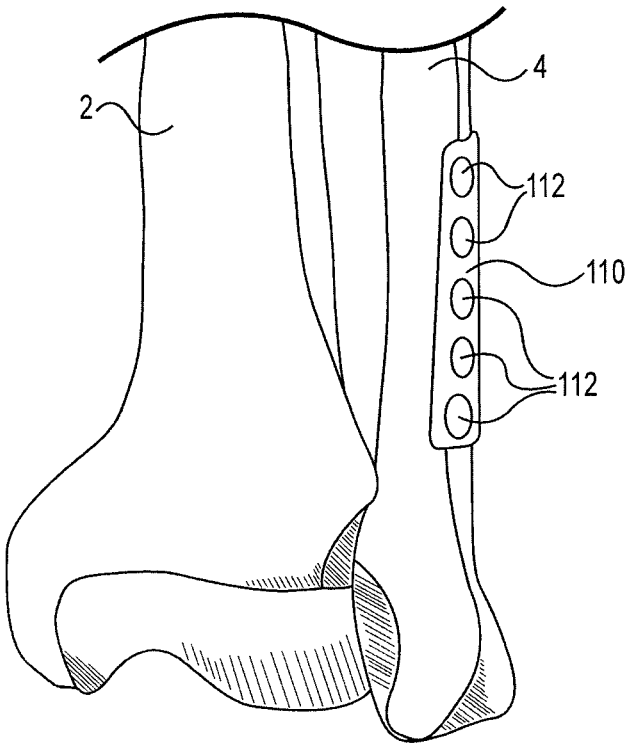


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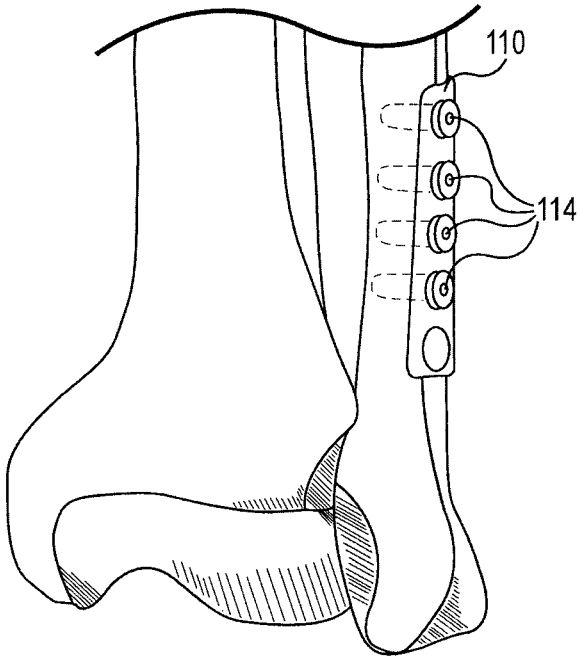


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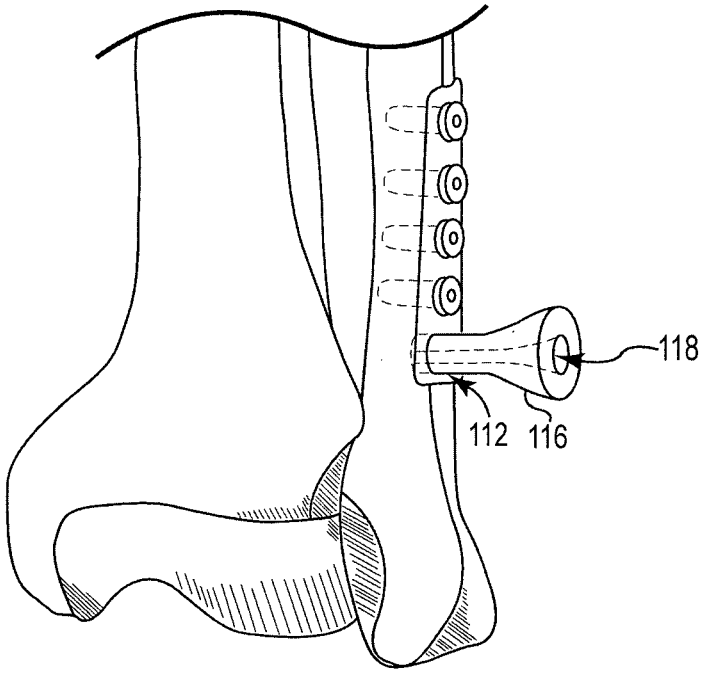


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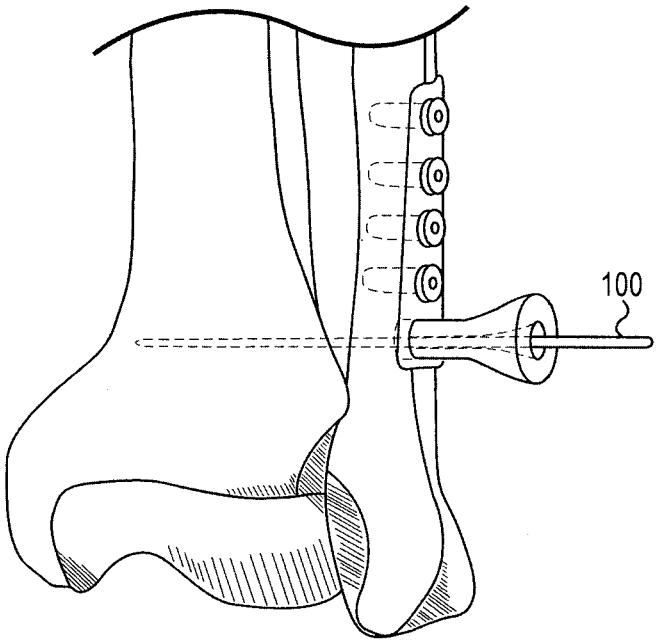


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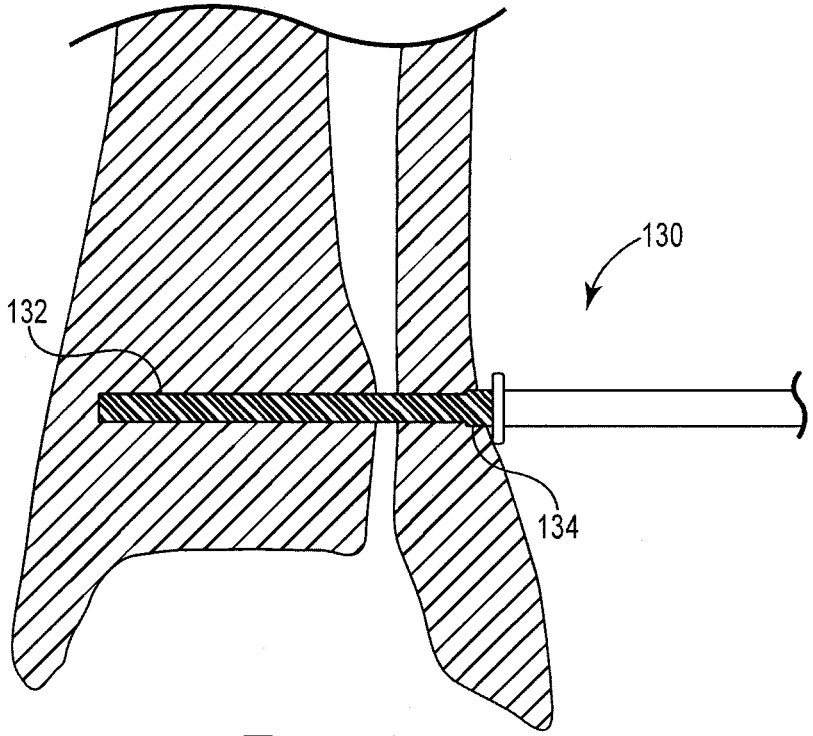


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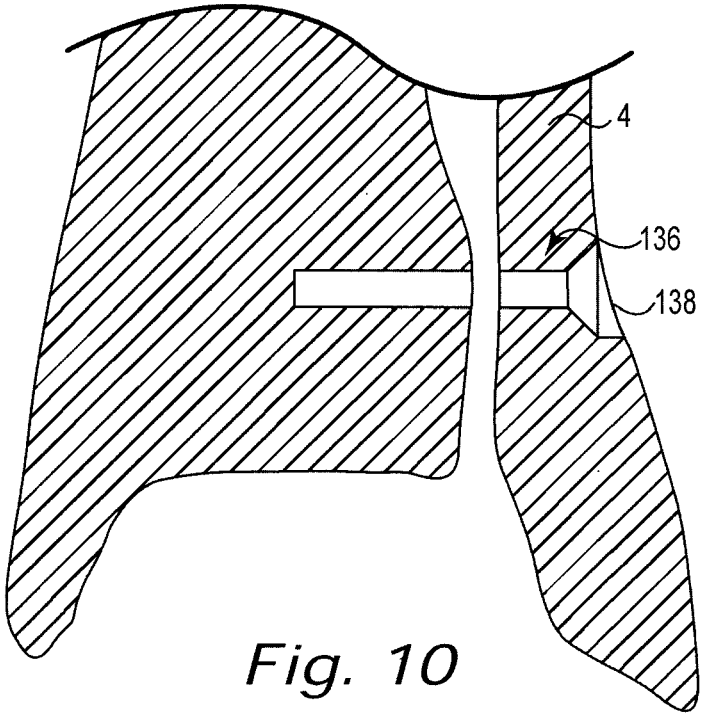


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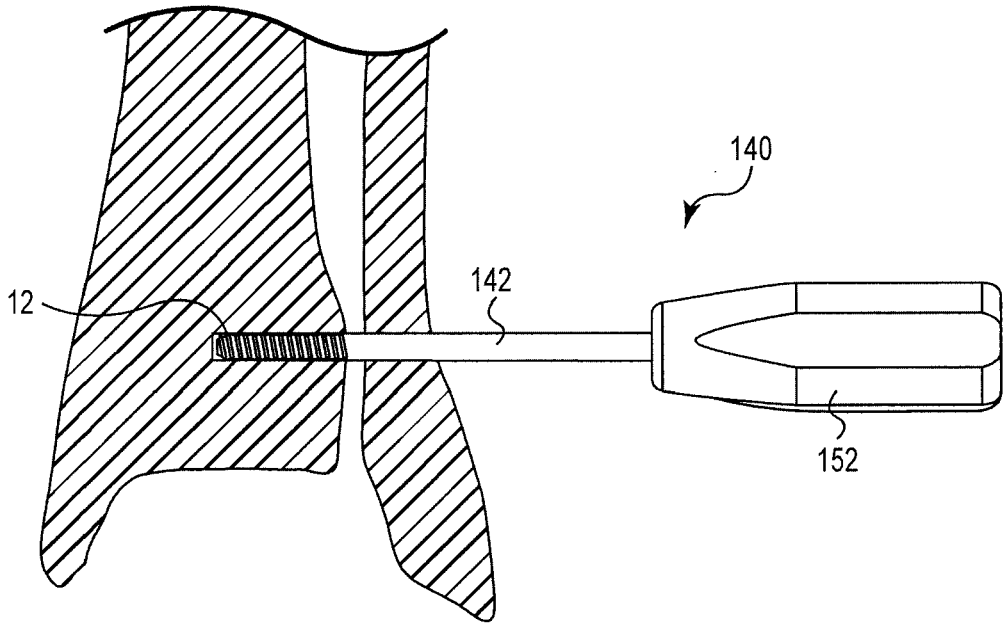


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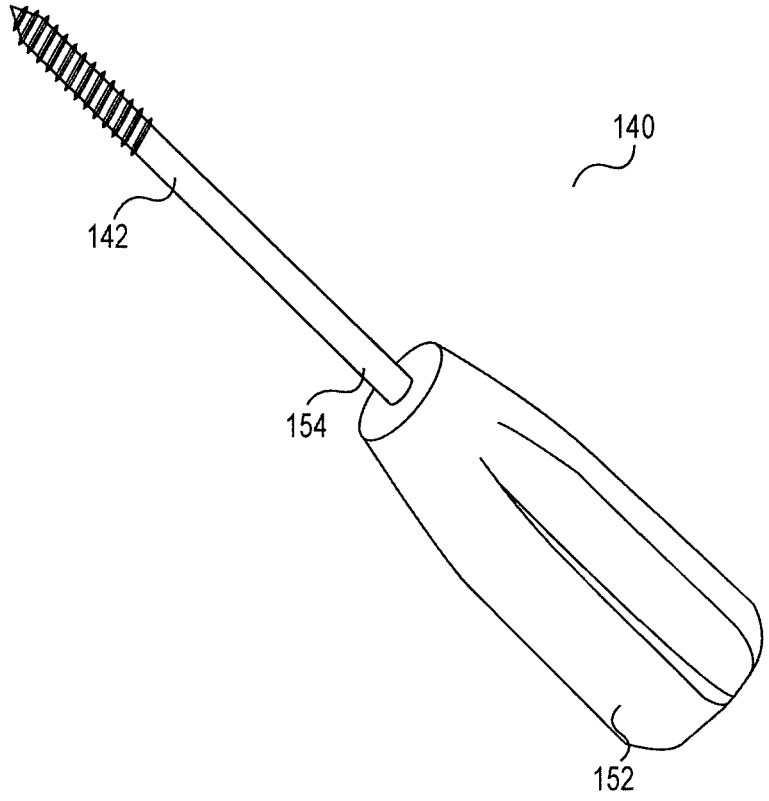


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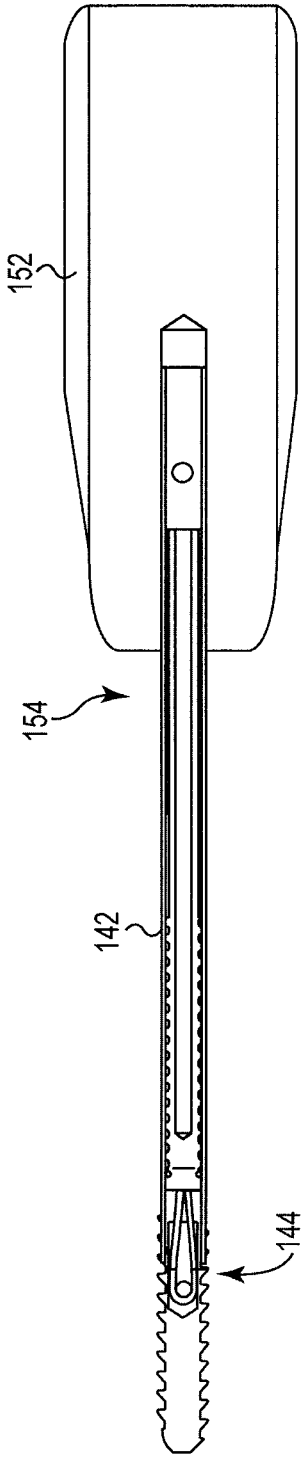


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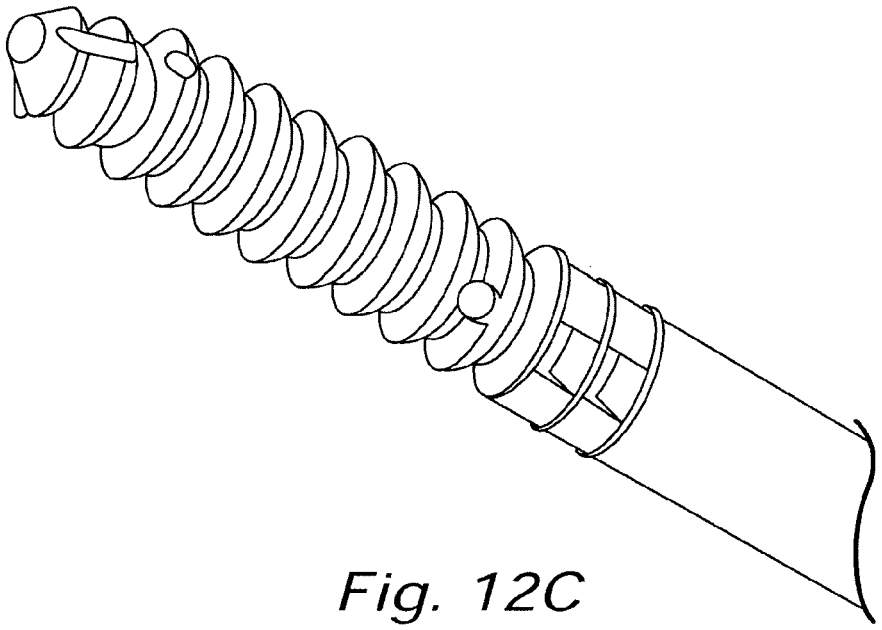

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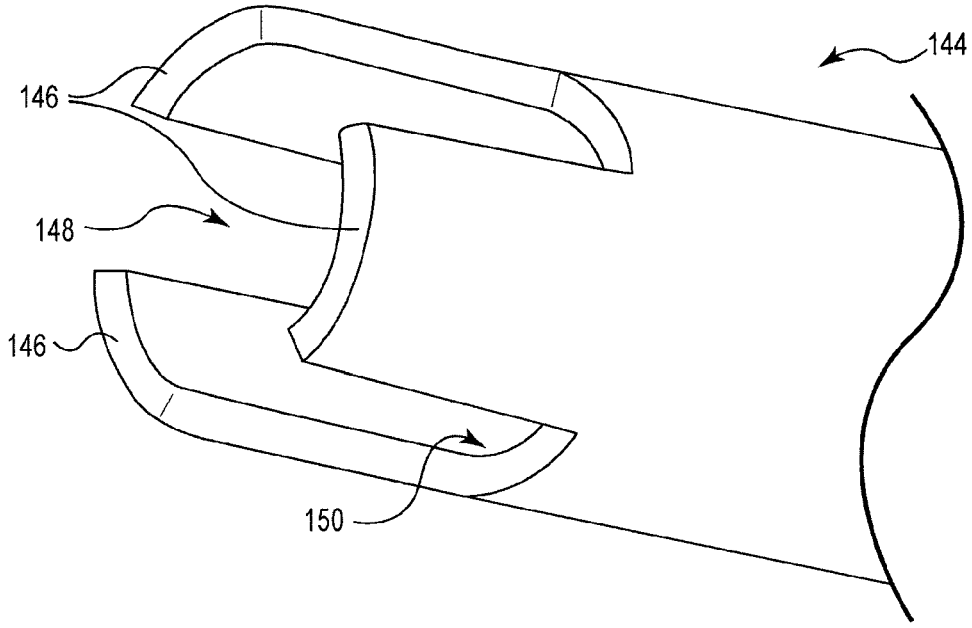


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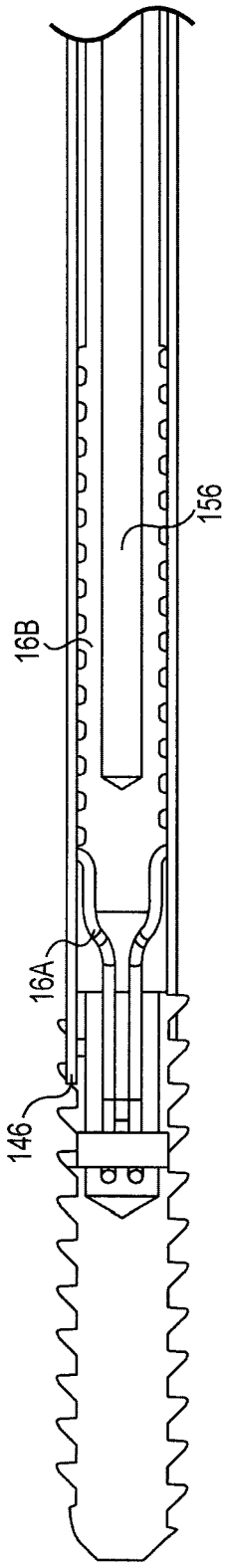


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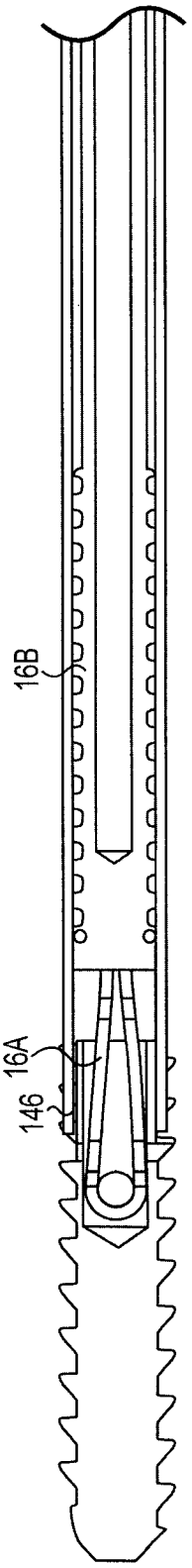


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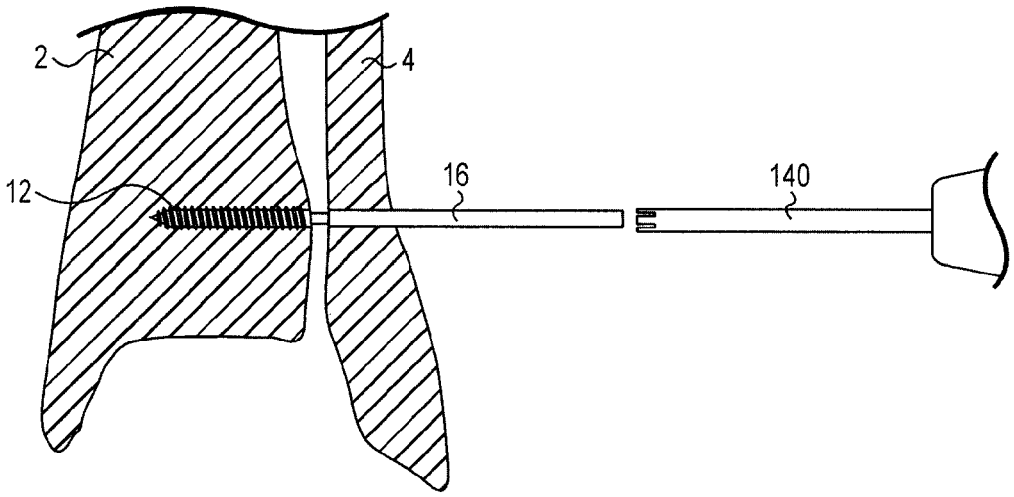


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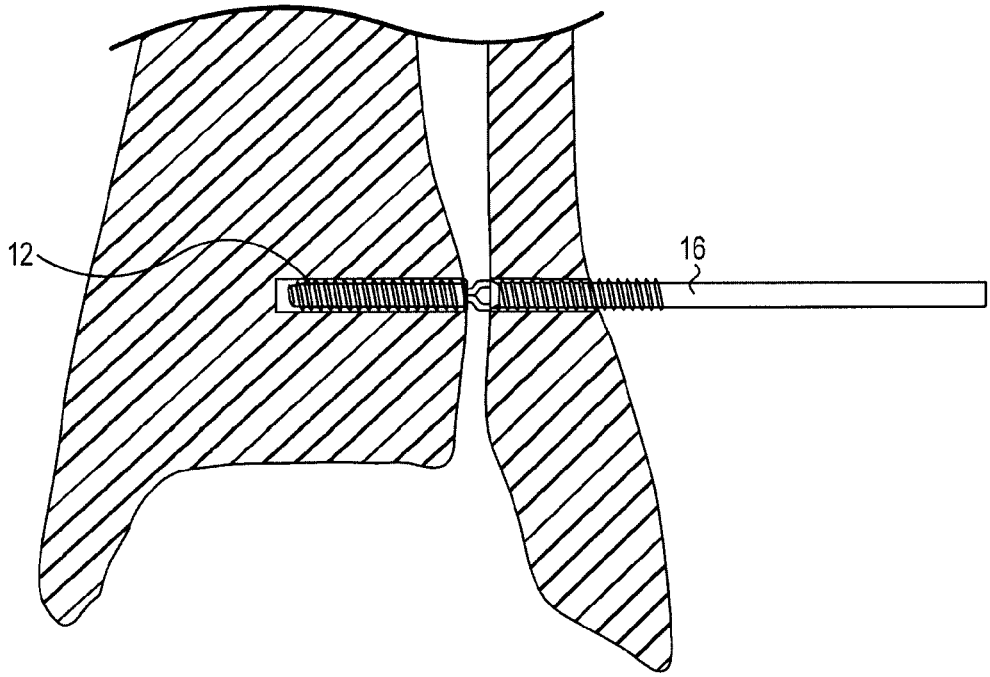


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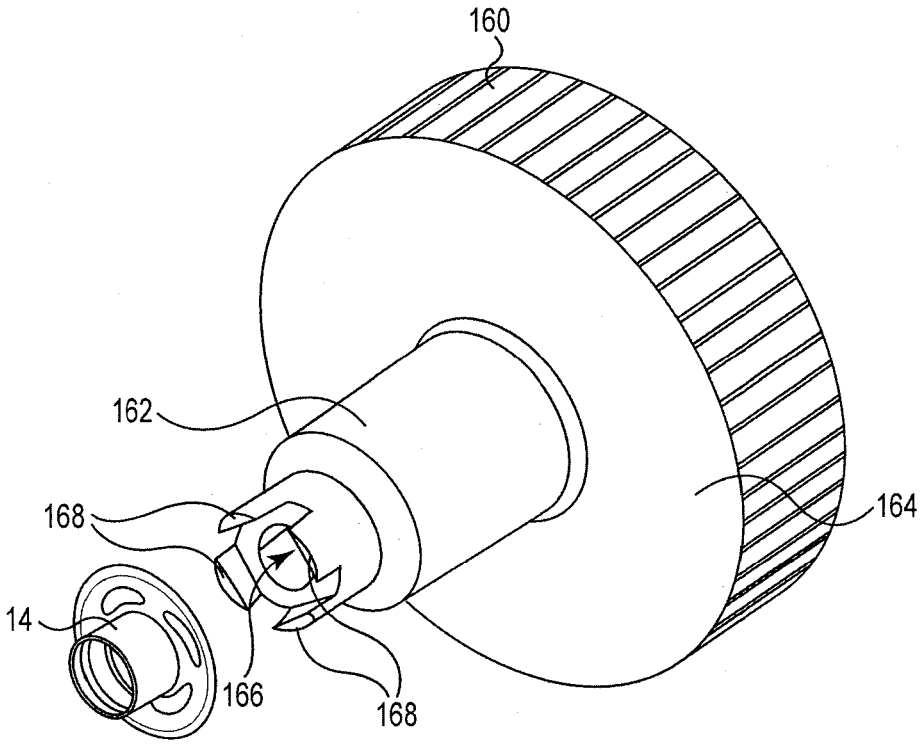


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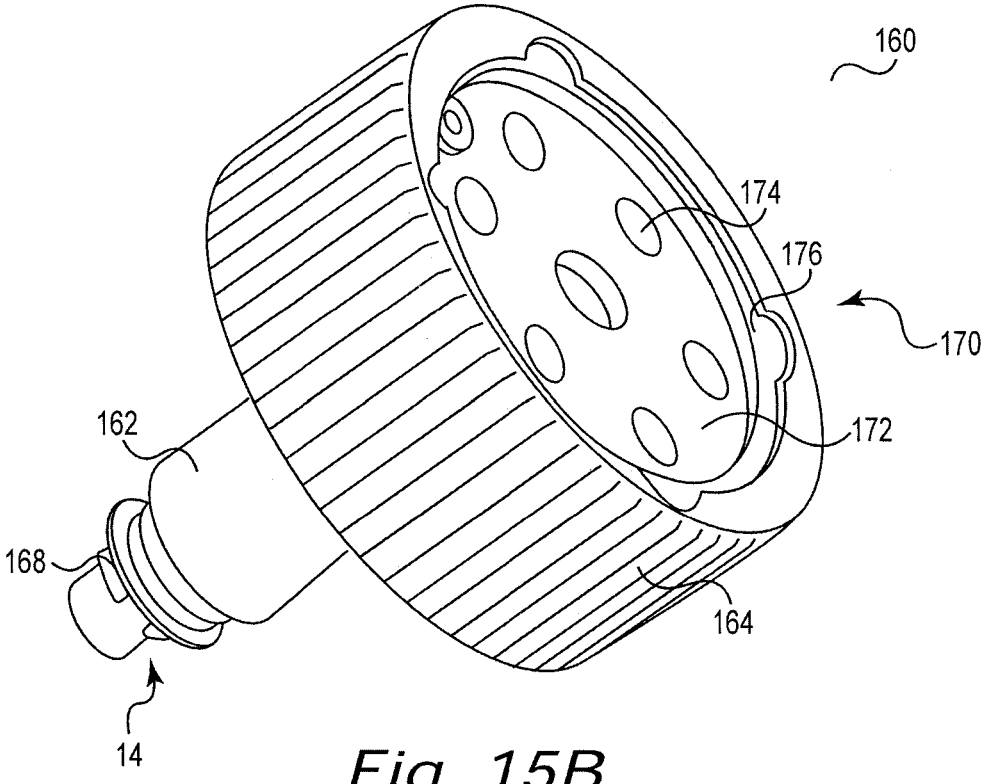


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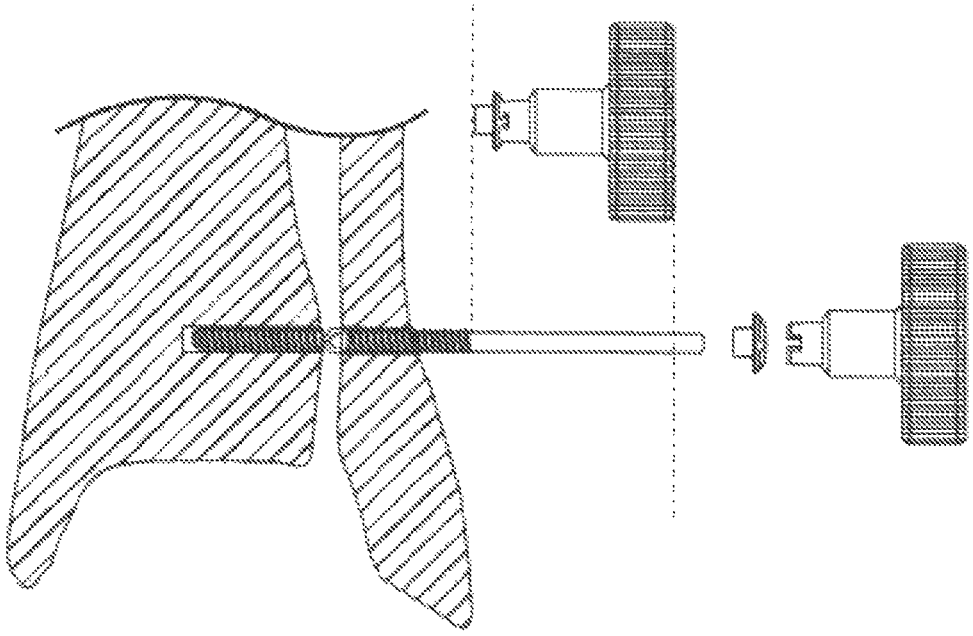

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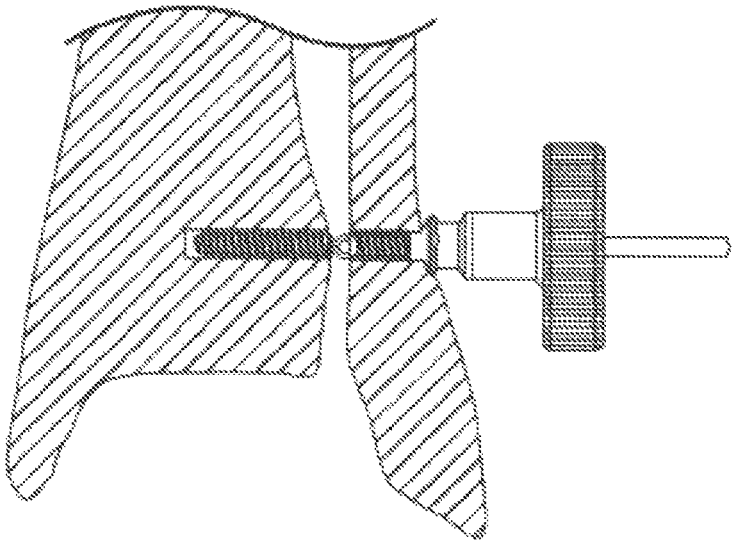

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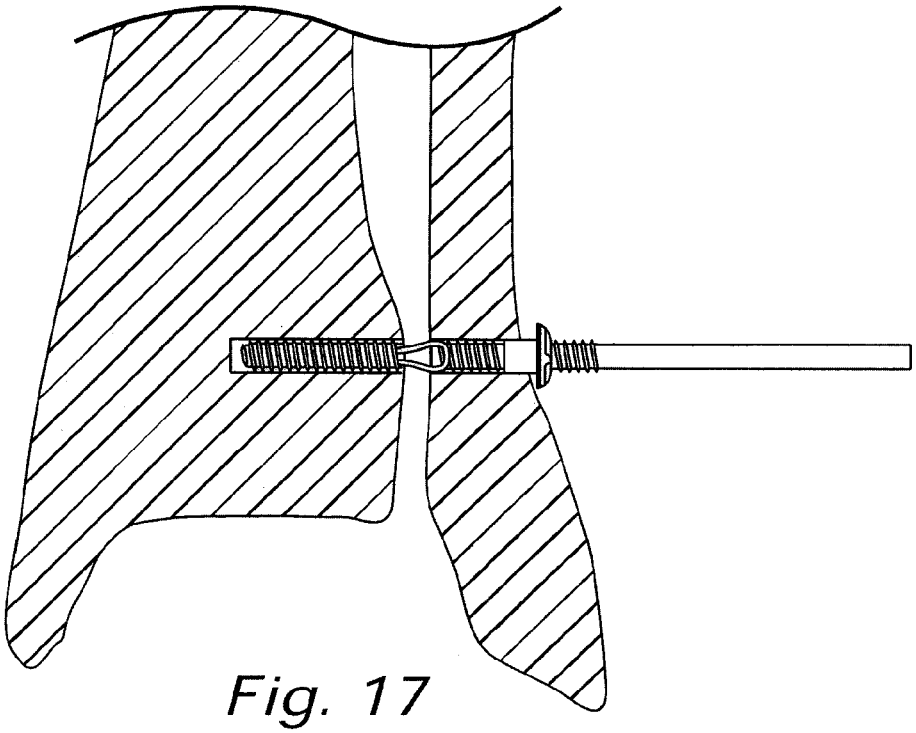

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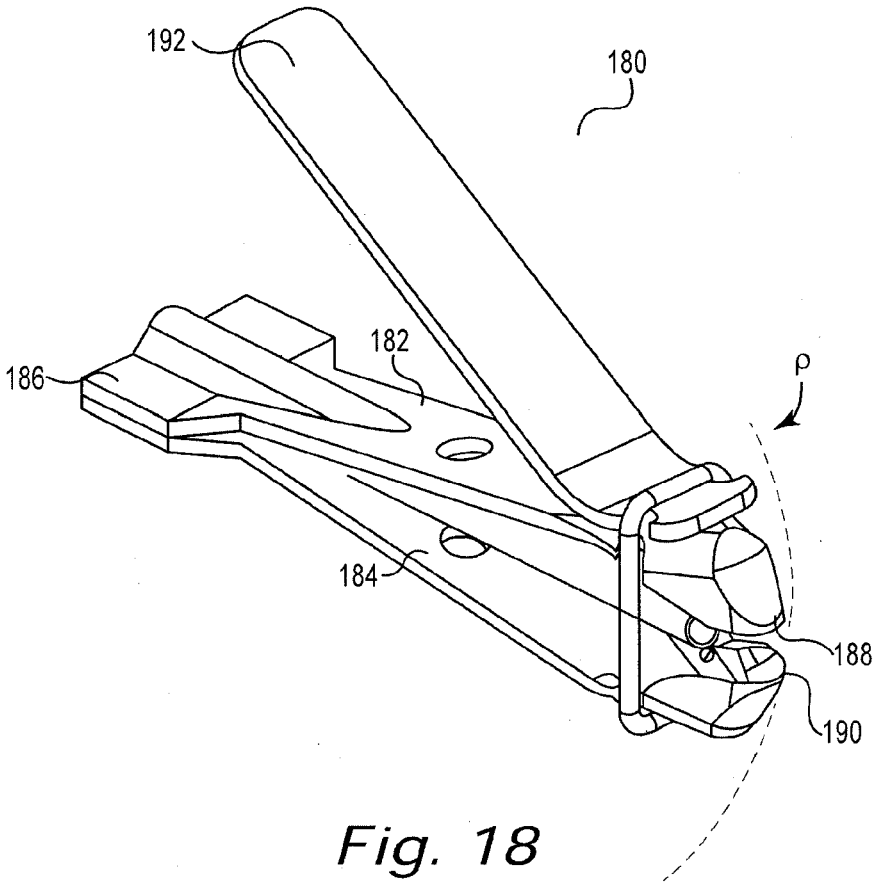


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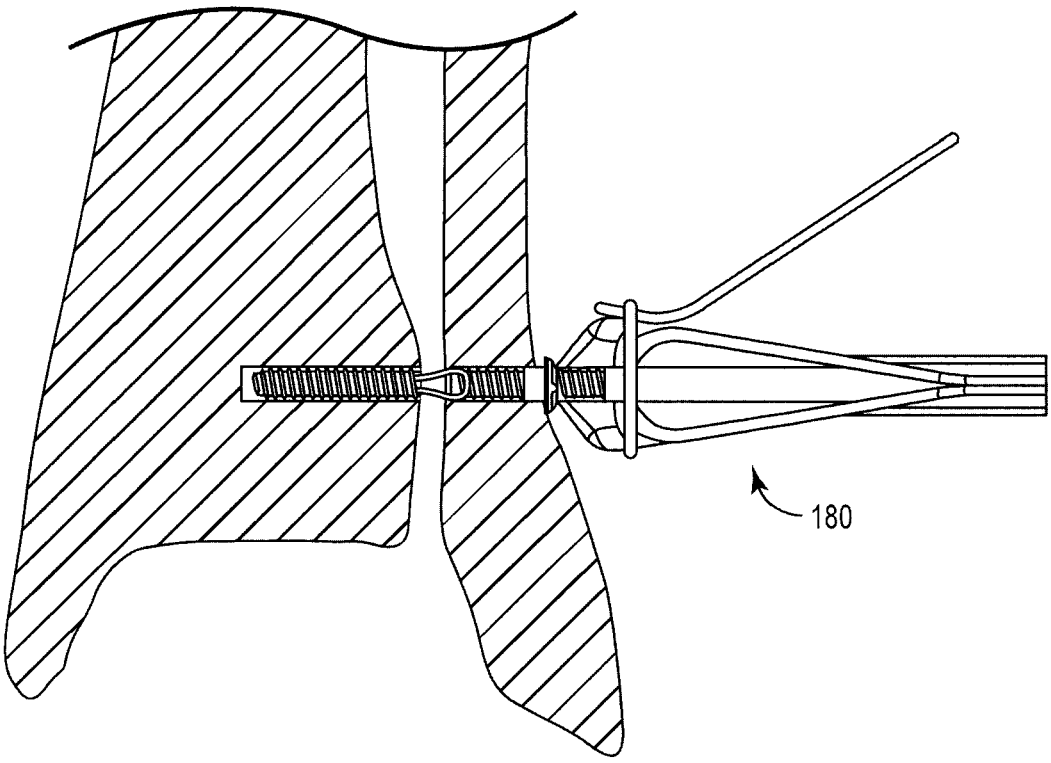


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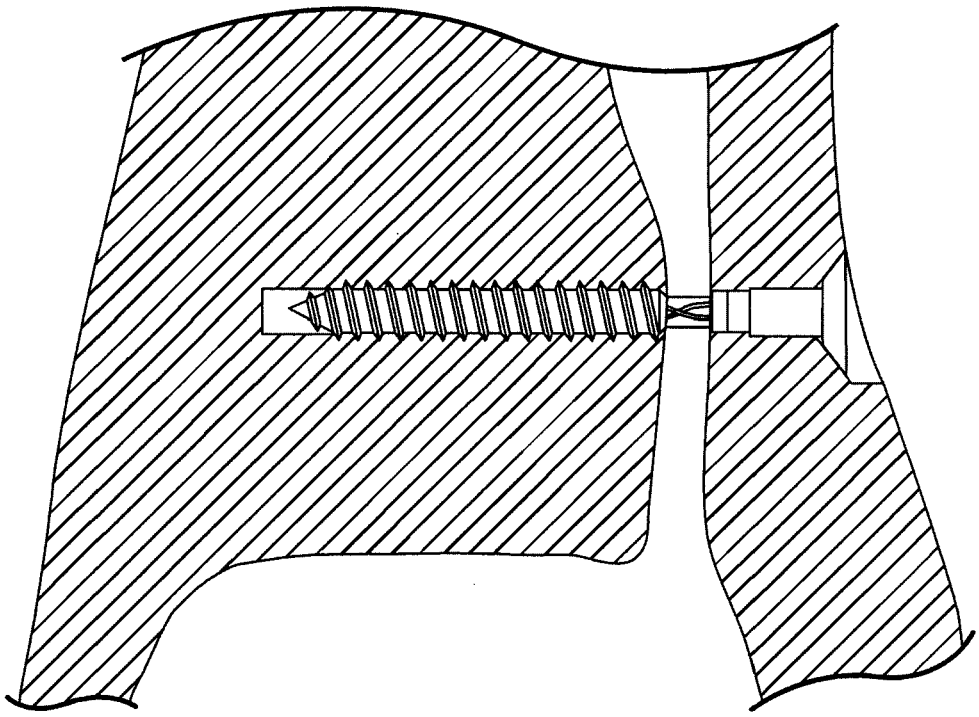

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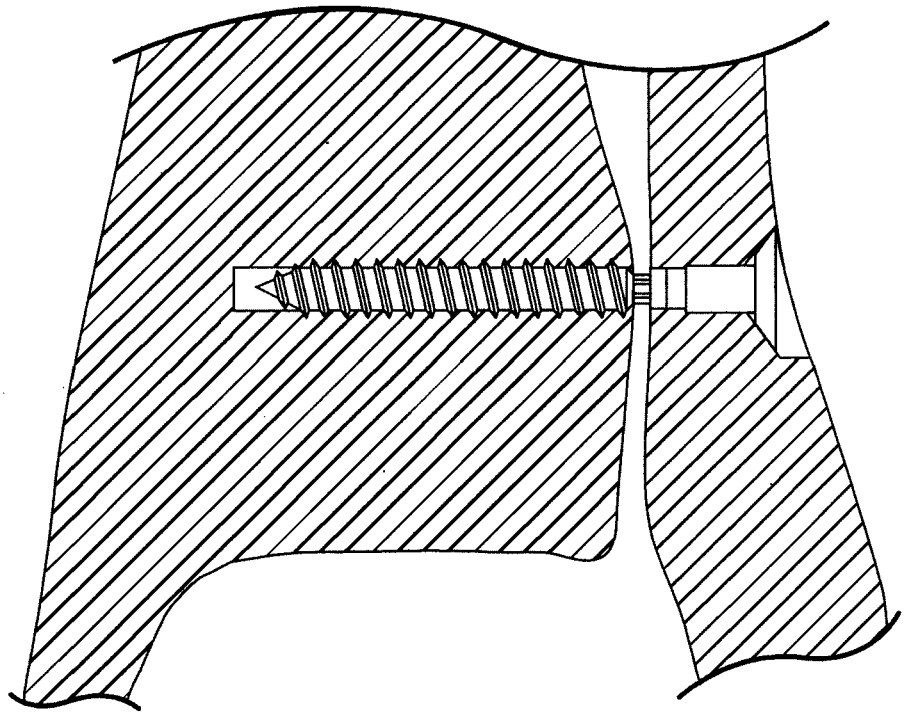

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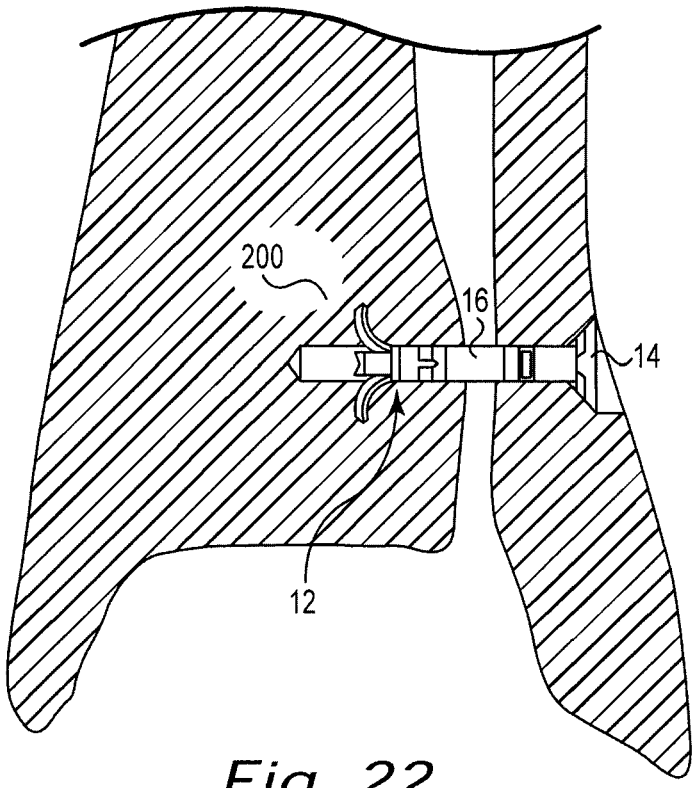


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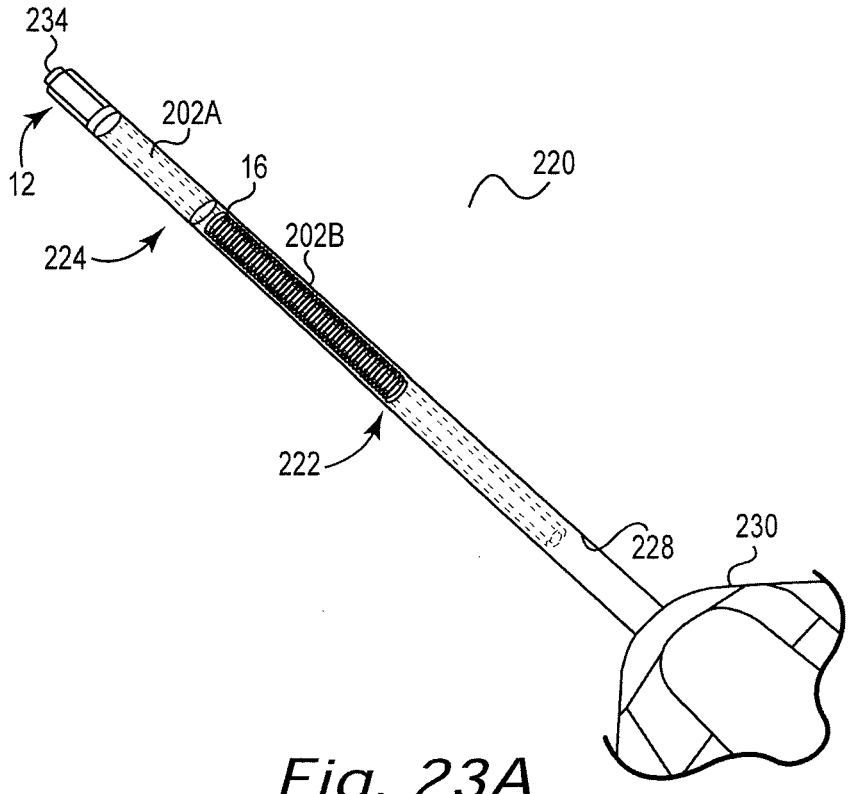


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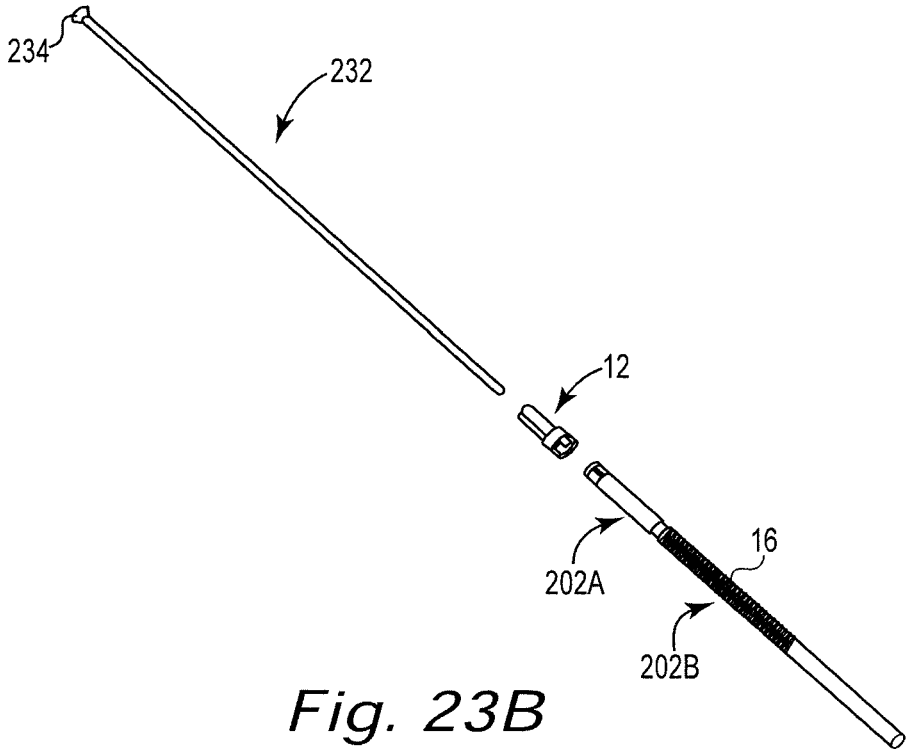


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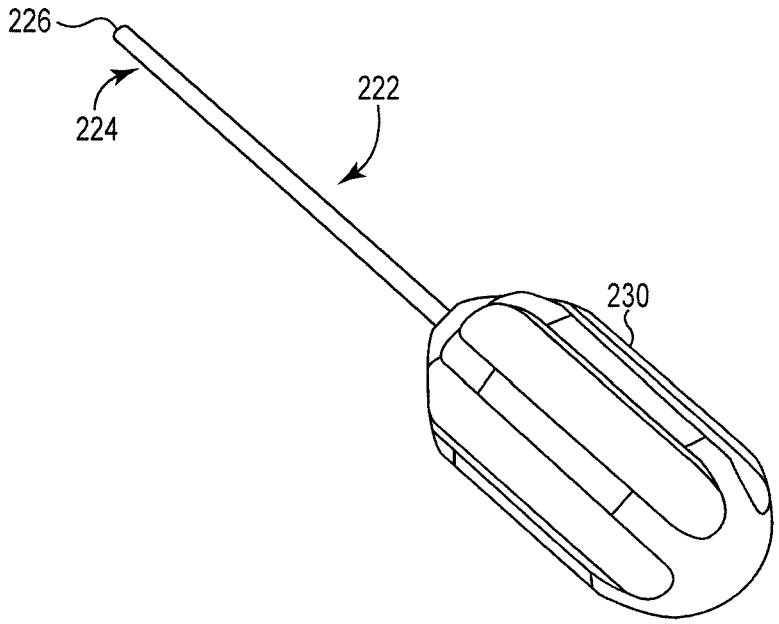


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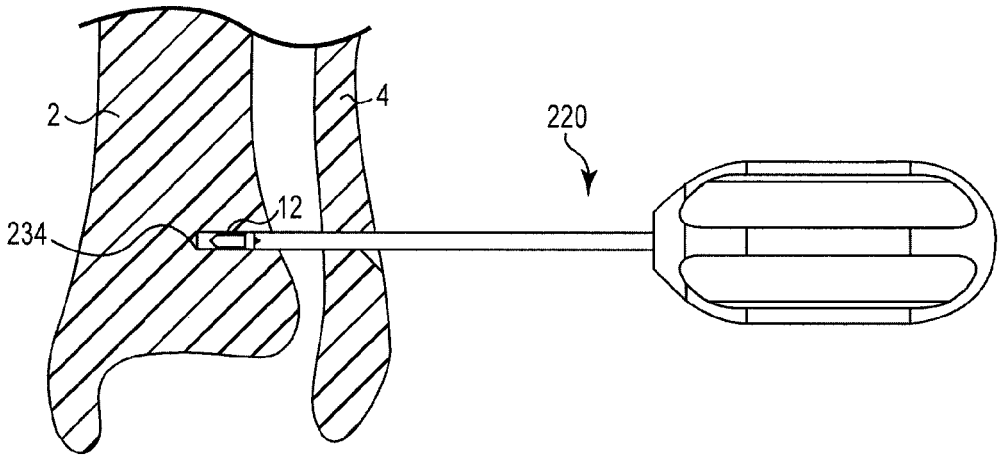


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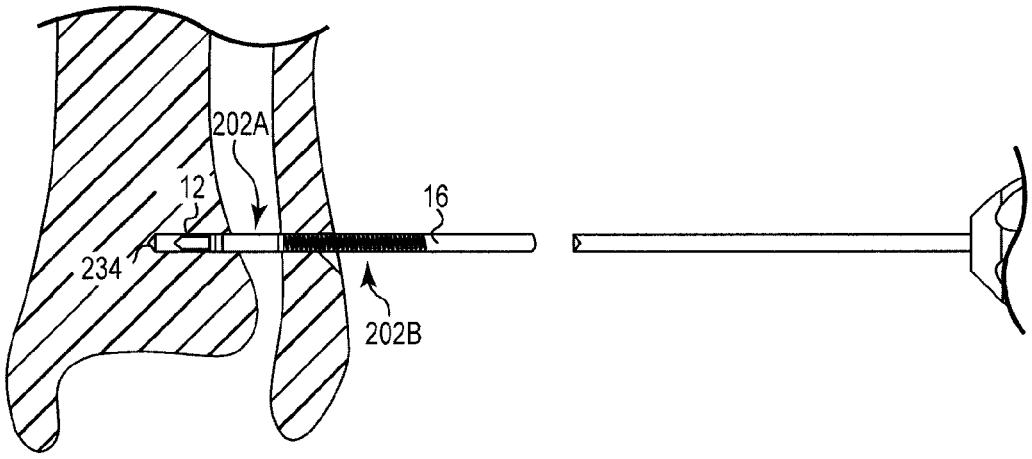


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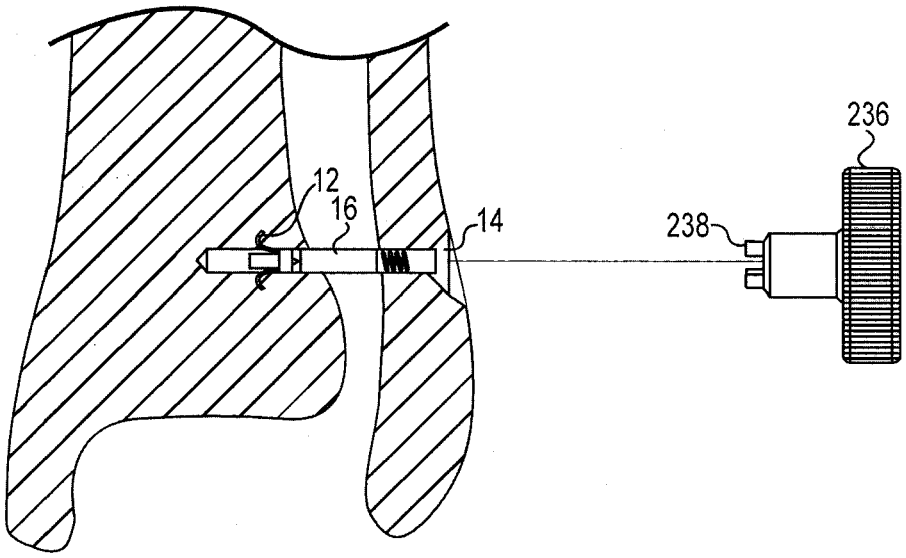


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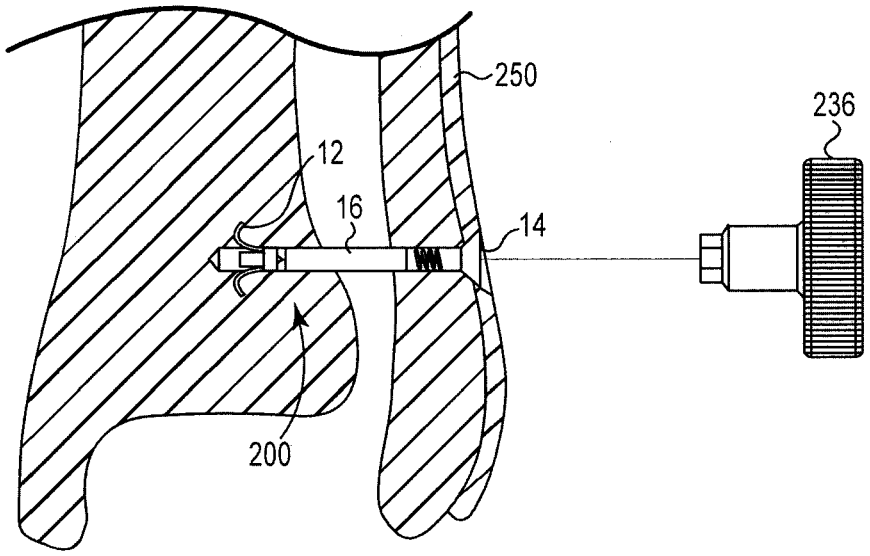


Fig. 24

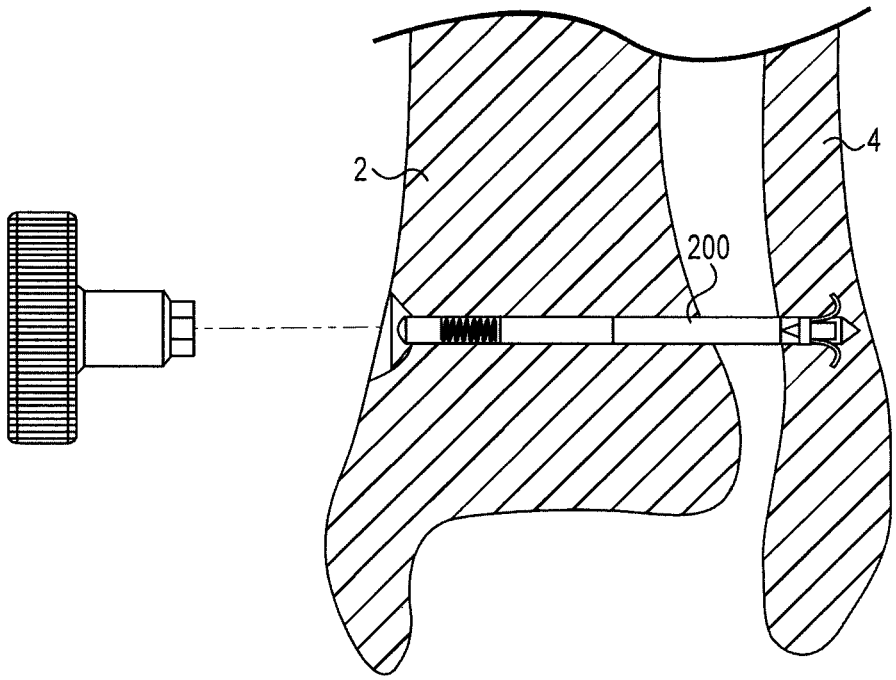


Fig. 25

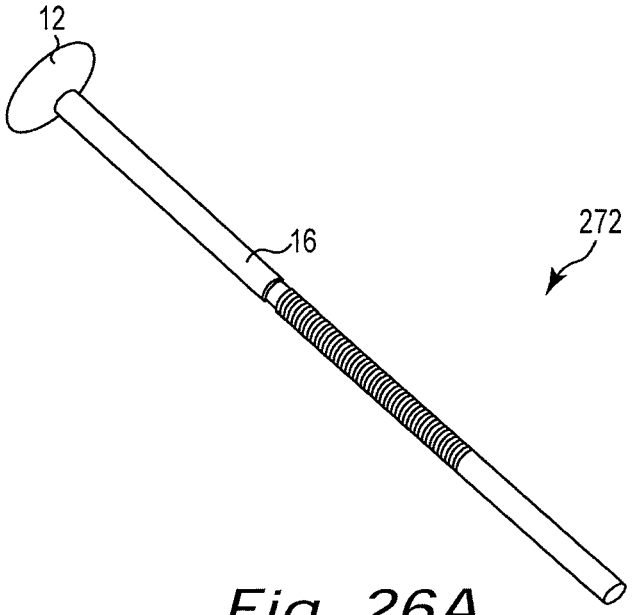


Fig. 26A

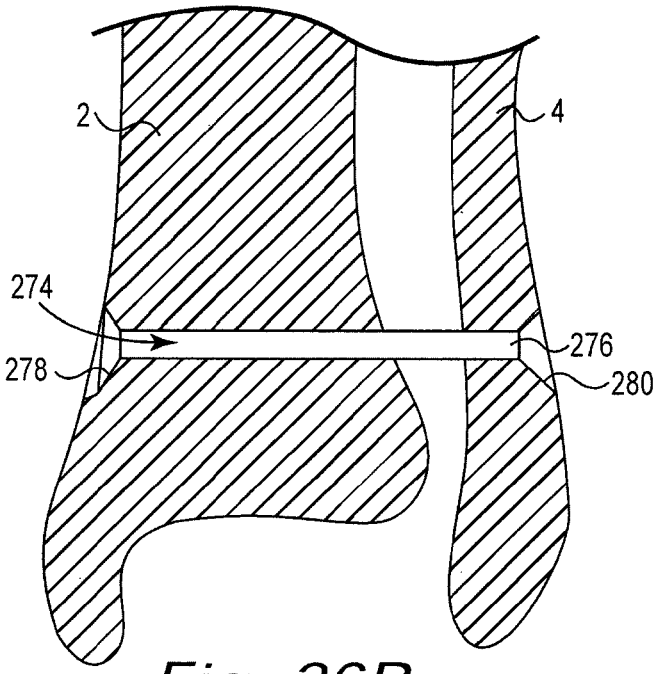


Fig. 26B

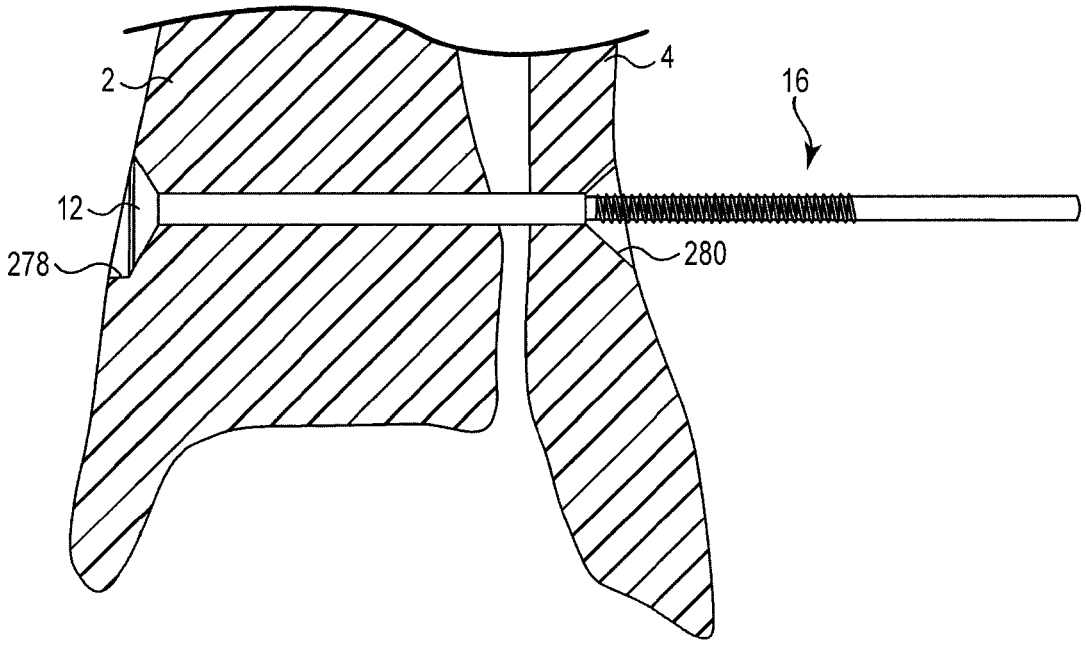


Fig. 26C

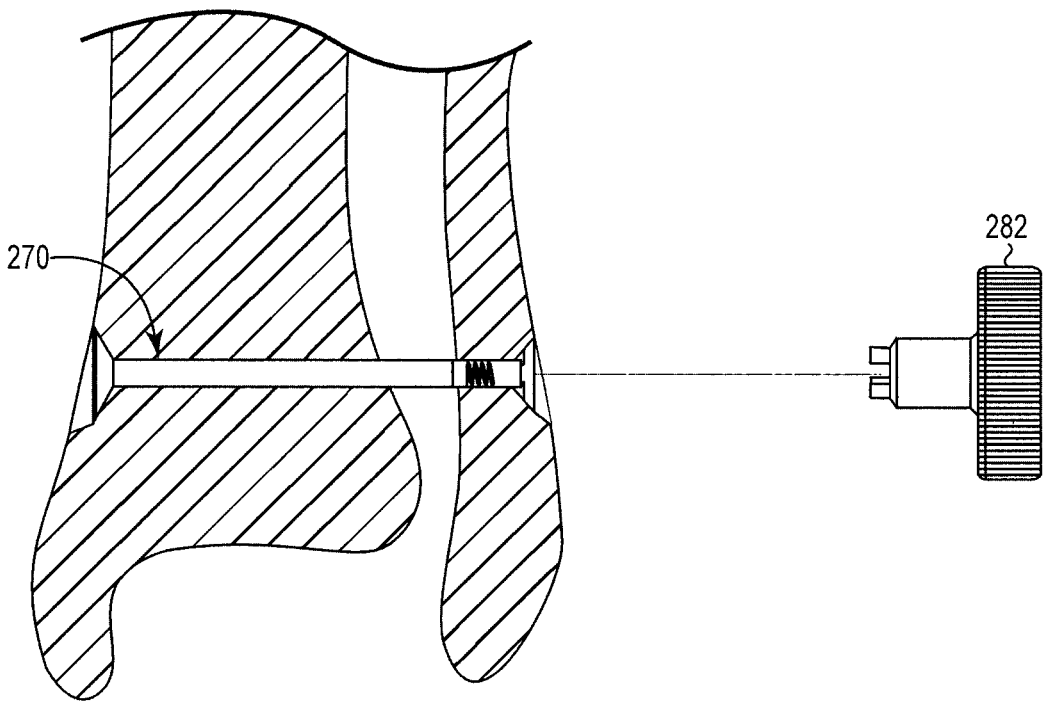


Fig. 26D

# METHODS AND DEVICES FOR TREATING A SYNDESMOSIS INJURY

## CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority to U.S. Provisional Application 61/428,051, filed Dec. 29, 2010 and entitled "Bone Approximation Devices and Methods," which is hereby incorporated herein by reference in its entirety.

## FIELD OF THE INVENTION

The various embodiments disclosed herein relate to methods and devices for treating a syndesmosis injury. Certain specific embodiments relate to systems and methods for correcting such an injury, including an ankle syndesmosis injury.

## BACKGROUND OF THE INVENTION

A syndesmosis is a type of joint. More specifically, a syndesmosis is a slightly movable articulation where contiguous bony surfaces are united by an interosseous ligament. An example is the inferior tibiofibular articulation of the ankle. This syndesmosis is made up of the anterior tibiofibular ligament, the interosseous ligament, and the posterior-fibular ligaments. Following trauma to the ankle, such as an ankle fracture, the syndesmotic joint can become unstable and painful. FIG. **1**A depicts an exemplary type of ankle fractures that can result in a syndesmotic joint injury. It is also understood that syndesmosis injury can also occur without fracture, such as with a severe ankle sprain. An example of this type of syndesmosis injury is depicted in FIG. **1**B, in which the ligaments have been torn without any bone fracture. The syndesmosis is identified in FIGS. **1**A and **1**B using the number "5." Surgery may be needed to stabilize the syndesmotic joint to allow these ligaments to properly heal. The current standard of care involves fixing the fibula to the tibia during the soft tissue healing process with one or two screws. Because these screws can inhibit normal joint motion, the screws are typically removed after the ligament injury is healed.

There is a need in the art for improved methods and devices for treating syndesmosis injuries, including ankle syndesmosis injuries.

## BRIEF SUMMARY OF THE INVENTION

Discussed herein are various treatment devices for treating syndesmosis injuries.

In Example 1, a method of treating a syndesmosis injury comprises positioning a first bone anchor through a second bone and into a first bone, wherein the first bone anchor is coupled to a first end of a tether, attaching the first bone anchor within the first bone, positioning a second bone anchor in the second bone and coupling the second bone anchor to a second end of the tether, urging the second bone anchor distally in relation to the tether with an anchor placement tool and thereby urging the second bone anchor toward the first bone anchor, examining a radiographic image to determine the initial position of the second bone in relation to the first bone, adjusting the positioning of the second bone anchor based on the initial position of the second bone in relation to the first bone to achieve a desired position, and removing the anchor placement tool.

Example 2 relates to the method of treating a syndesmosis injury according to Example 1, wherein attaching the first bone anchor with the first bone further comprises deploying prongs within the first bone, wherein the prongs are operably coupled to the first bone anchor.

Example 3 relates to the method of treating a syndesmosis injury according to Example 1, wherein urging the second bone anchor distally in relation to the tether further comprises rotating the anchor placement tool and thereby rotating the second bone anchor.

Example 4 relates to the method of treating a syndesmosis injury according to Example 1, wherein positioning a first bone anchor further comprises positioning a deployment assembly through a hole formed in the second bone and into contact with the first bone. The deployment assembly comprises an outer tube, the tether disposed within the outer tube, the tether comprising a flexible component and a base component coupled to the flexible component, the first bone anchor disposed at the distal end of the outer tube, the first bone anchor being coupled to the first end of the flexible component, and a deployment tube disposed within the outer tube, the deployment tube comprising a deployment anvil disposed at the distal end of the deployment tube.

Example 5 relates to the method of treating a syndesmosis injury according to Example 4, wherein the deploying the prongs comprises urging the deployment tube in a proximal direction in relation to the outer tube, whereby the deployment anvil is urged against the first bone anchor.

Example 6 relates to the method of treating a syndesmosis injury according to Example 3, wherein the coupling the second bone anchor to the second end of the tether further comprises coupling the second bone anchor to a proximal end of the base component.

Example 7 relates to the method of treating a syndesmosis injury according to Example 5, wherein the coupling the second bone anchor to the proximal end of the base component further comprises using an anchor placement tool to couple the second bone anchor to the proximal end of the base component.

Example 8 relates to the method of treating a syndesmosis injury according to Example 1, the method further comprising forming a hole in the second bone prior to positioning the first bone anchor in the first bone.

Example 9 relates to the method of treating a syndesmosis injury according to Example 1, the method further comprising first positioning a guide wire through the second bone and into the first bone, wherein the positioning the first bone anchor comprises positioning the first bone anchor over the guide wire.

Example 10 relates to the method of treating a syndesmosis injury according to Example 1, wherein positioning the first bone anchor into the first bone further comprises positioning the first bone anchor into the first bone such that a proximal end of the first bone anchor is substantially flush with a surface of the first bone.

In Example 11, a method of treating a syndesmosis injury comprises positioning a first bone anchor through a second bone and into a first bone, wherein the first bone anchor is coupled to a first end of a tether, attaching the first bone anchor within the first bone, positioning a second bone anchor in the second bone and coupling the second bone anchor to a second end of the tether, urging the second bone anchor distally in relation to the tether with an anchor placement tool and thereby urging the second bone anchor toward the first bone anchor, evaluating ankle function to determine the initial position of the second bone in relation to the first bone, adjusting the positioning of the second bone anchor based on

the initial position of the second bone in relation to the first bone to achieve a desired position, and removing the anchor placement tool.

In Example 12, a method of treating a syndesmosis injury comprises forming a hole through a second bone and into a first bone, inserting a deployment assembly into the hole in the second bone, positioning the first bone anchor in the first bone, removing the deployment assembly, and coupling a second bone anchor to a second end of the tether and positioning the second bone anchor in the second bone. The deployment assembly comprises an outer tube, a tether disposed within the outer tube, and a first bone anchor disposed at the distal end of the outer tube, the first bone anchor being coupled to the first end of the flexible component. The tether comprises a flexible component, and a base component coupled to the flexible component.

Example 13 relates to the method of treating a syndesmosis injury according to Example 12, wherein the positioning the first bone anchor further comprises rotating the deployment assembly to drill the first bone anchor into the first bone.

Example 14 relates to the method of treating a syndesmosis injury according to Example 12, further comprising urging the second bone anchor distally in relation to the tether, thereby urging the second bone anchor toward the first bone anchor.

Example 15 relates to the method of treating a syndesmosis injury according to Example 12, further comprising first positioning a guide wire through the second bone and into the first bone, wherein the forming the hole in the second bone further comprises positioning a drill over the guide wire and drilling the hole in the second bone, and wherein the inserting the deployment assembly into the hole further comprises inserting the deployment assembly over the guide wire.

In Example 16, a method of treating a syndesmosis injury comprises forming a hole through a fibula bone and into a tibia bone, inserting a deployment assembly into the hole in the fibula bone, positioning the first bone anchor in the tibia bone using the deployment assembly, removing the deployment assembly, and coupling a second bone anchor to a second end of the tether and positioning the second bone anchor in the fibula bone. The deployment assembly comprises an outer tube comprising at least two prongs at a distal end of the outer tube, a tether disposed within the outer tube, and a first bone anchor disposed at the distal end of the outer tube. The tether comprises a flexible component and a base component coupled to the flexible component. The first bone anchor comprises external threads defined on an external portion of the first bone anchor, and at least two openings defined in the threads at a proximal end of the first bone anchor, the at least two openings configured to receive the at least two prongs of the outer tube.

Example 17 relates to the method of treating a syndesmosis injury according to Example 16, wherein the external threads are defined on substantially all of the external portion of the first bone anchor.

Example 18 relates to the method of treating a syndesmosis injury according to Example 16, further comprising positioning the second bone anchor with an anchor placement tool, examining a radiographic image or evaluating ankle function to determine the initial position of the second bone in relation to the first bone, adjusting the positioning of the second bone anchor based on the initial position of the second bone in relation to the first bone to achieve a desired position, and removing the anchor placement tool.

Example 19 relates to the method of treating a syndesmosis injury according to Example 18, wherein the positioning and the adjusting of the positioning of the second bone anchor comprises rotating the anchor placement tool and thereby rotating the second bone anchor.

Example 20 relates to the method of treating a syndesmosis injury according to Example 16, wherein the second bone anchor comprises a head comprising at least two openings.

Example 21 relates to the method of treating a syndesmosis injury according to Example 20, wherein the anchor placement tool comprises at least two prongs configured to be positionable within the at least two openings in the head of the second bone anchor.

In Example 22, a method of treating a syndesmosis injury comprises positioning a first bone anchor through a second bone and into a first bone, wherein the first bone anchor is coupled to a first end of a tether, urging the first bone anchor into the first bone with a deployment tool, positioning a second bone anchor in the second bone and coupling the second bone anchor to a second end of the tether, and urging the second bone anchor distally in relation to the tether with an anchor placement tool, thereby urging the second bone anchor toward the first bone anchor until the second bone anchor is positioned as desired. The first bone anchor comprises external threads defined along an entire length of an external portion of the first bone anchor, wherein the external threads are configured to be engageable with a cortical surface of the first bone, and at least two openings defined in the external threads at a proximal end of the first bone anchor, the at least two openings configured to receive at least two prongs of the deployment tool.

Example 23 relates to the method of treating a syndesmosis injury according to Example 22, wherein the first bone anchor further comprises a lumen defined within the first bone anchor, and a opening at a distal end of the first bone anchor, wherein the opening is in communication with the lumen, and further wherein the urging the first bone anchor into the first bone with the deployment tool further comprises urging the first bone anchor into the first bone without operably coupling the deployment tool with the opening or the lumen.

While multiple embodiments are disclosed, still other embodiments of the present invention will become apparent to those skilled in the art from the following detailed description, which shows and describes illustrative embodiments of the invention. As will be realized, the invention is capable of modifications in various obvious aspects, all without departing from the spirit and scope of the present invention. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not restrictive.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1**A is a schematic depiction of a syndesmosis injury with a bone fracture.

FIG. **1**B is a schematic depiction of a syndesmosis injury without a fracture.

FIG. **2** is a schematic depiction of an implantable syndesmosis injury treatment device implanted in a patient, according to one embodiment.

FIG. **3**A is a side view of a first anchor, according to one embodiment.

FIG. **3**B is a perspective view of the first anchor of FIG. **3**A, according to one embodiment.

FIG. **3**C is a rear view of the first anchor of FIG. **3**A, according to one embodiment.

FIG. **4** is a perspective view of a distal end of a first anchor, according to another embodiment.

FIG. **5**A is a side view of a tether, according to one embodiment.

FIG. **5**B is an expanded cross-sectional side view of a first anchor coupled to a flexible component and a deployment tool (also referred to herein as an "implantation tool"), according to one embodiment.

FIG. **5**C is an expanded cross-sectional side view of a first anchor coupled to flexible component that is coupled to a base component, according to one embodiment.

FIG. **5**D is a perspective view of a flexible component coupled to a base component, according to one embodiment.

FIG. **5**E is a side view of the flexible component coupled to the base component of FIG. **5**D, according to one embodiment.

FIG. **5**F is a perspective view of a plug, according to one embodiment.

FIG. **5**G is a perspective view of the plug of FIG. **5**F coupled to a first anchor and a tether, according to one embodiment.

FIG. **6**A is a perspective top view of a second anchor, according to one embodiment.

FIG. **6**B is a perspective bottom view of the second anchor of FIG. **6**A, according to one embodiment.

FIG. **6**C is a side view of a second anchor, according to another embodiment.

FIG. **6**D is a side view of a second anchor, according to a further embodiment.

FIG. **6**E is a side view of a second anchor, according to yet another embodiment.

FIG. **7** is a schematic depiction of a tibia and fibula, in which a guidewire has been positioned through the fibula and into the tibia, according to one embodiment.

FIG. **8**A is a schematic depiction of a tibia and fibula, in which a fixation plate has been positioned on the fibula, according to one embodiment.

FIG. **8**B is a schematic depiction of the tibia and fibula of FIG. **8**A, in which screws have been positioned through the fixation plate, according to one embodiment.

FIG. **8**C is a schematic depiction of the tibia and fibula of FIG. **8**A, in which a wire guide has been positioned into the fixation plate, according to one embodiment.

FIG. **8**D is a schematic depiction of the tibia and fibula of FIG. **8**A, in which guidewire has been positioned through the fixation plate and into the bones, according to one embodiment.

FIG. **9** is a schematic depiction of a drill positioned in a tibia and fibula, according to one embodiment.

FIG. **10** is a schematic depiction of a hole created by a drill in a tibia and fibula, according to one embodiment.

FIG. **11** is a schematic depiction of a deployment tool and first anchor being positioned into a tibia and fibula, according to one embodiment.

FIG. **12**A is a perspective view of a deployment tool and first anchor, according to one embodiment.

FIG. **12**B is a cross-sectional side view of the deployment tool and first anchor of FIG. **12**A, according to one embodiment.

FIG. **12**C is a perspective view of the distal end of the deployment tool and first anchor of FIG. **12**A, according to one embodiment.

FIG. **12**D is a perspective view of the distal end of the deployment tool of FIG. **12**A, according to one embodiment.

FIG. **12**E is a cross-sectional side view of the distal end of the deployment tool and first anchor of FIG. **12**A, according to one embodiment.

FIG. **12**F is another cross-sectional side view of the distal end of the deployment tool and first anchor of FIG. **12**A, according to one embodiment.

FIG. **13** is a schematic depiction of a deployment tool being removed after positioning a first anchor and tether in a tibia and fibula, according to one embodiment.

FIG. **14** is a schematic depiction of a first anchor and tether positioned in a tibia and fibula, according to one embodiment.

FIG. **15**A is a perspective view of a driver tool, according to one embodiment.

FIG. **15**B is another perspective view of the driver tool of FIG. **15**A, according to another embodiment.

FIG. **16**A is a schematic depiction of a first anchor and tether positioned in a tibia and fibula with a second anchor and driver tool prior to positioning of the second anchor onto the tether, according to one embodiment.

FIG. **16**B is a schematic depiction of the first anchor and tether positioned in the tibia and fibula of FIG. **16**A with the second anchor and driver tool positioned on the tether, according to one embodiment.

FIG. **17** is a schematic depiction of the first anchor, tether, and second anchor implanted in the tibia and fibula of FIG. **16**A prior to removal of the excess tether, according to one embodiment.

FIG. **18** is a perspective view of a cutting tool, according to one embodiment.

FIG. **19** is a schematic depiction of the first anchor, tether, and second anchor implanted in the tibia and fibula of FIG. **16**A with a cutting tool positioned over the excess tether, according to one embodiment.

FIG. **20** is a schematic depiction of an implantable syndesmosis injury treatment device implanted in a patient, according to one embodiment.

FIG. **21** is a schematic depiction of another implantable syndesmosis injury treatment device implanted in a patient in which the distance between the tibia and fibula has been reduced, according to one embodiment.

FIG. **22** is a schematic depiction of an alternative implantable syndesmosis injury treatment device having deployable prongs implanted in a patient, according to one embodiment.

FIG. **23**A is a perspective, cutaway view of a deployment tool and first anchor having deployable prongs, according to an alternative embodiment.

FIG. **23**B is a perspective view of various parts of the deployment tool and first anchor depicted in FIG. **23**A, according to one embodiment.

FIG. **23**C is a perspective view of the deployment tool of FIG. **23**A, according to one embodiment.

FIG. **23**D is a schematic depiction of the first anchor and deployment tool of FIG. **23**A positioned in a tibia and fibula, according to one embodiment.

FIG. **23**E is a schematic depiction of the first anchor and tether of FIG. **23**A positioned in a tibia and fibula with the deployment tool being removed, according to one embodiment.

FIG. **23**F is a schematic depiction of the implantable device of FIG. **23**A implanted in the tibia and fibula with the anchor driving tool being removed, according to one embodiment.

FIG. **24** is a schematic depiction of another implantable device implanted in the tibia and fibula through a fixation plate with the anchor driving tool being removed, according to another embodiment.

FIG. **25** is a schematic depiction of another implantable device implanted in the tibia and fibula in a reverse orientation in comparison to the prior embodiments with the anchor driving tool being removed, according to another alternative embodiment.

FIG. **26**A is a perspective view of a first anchor and tether, according to yet another alternative embodiment.

FIG. **26**B is a schematic depiction of holes in the tibia and fibula, according to a further alternative embodiment.

FIG. **26**C is a schematic depiction of the first anchor and tether of FIG. **26**A positioned through a tibia and fibula, according to one embodiment.

FIG. **26**D is a schematic depiction of the first anchor and tether of FIG. **26**A implanted with a second anchor into a tibia and fibula with the anchor driving tool being removed, according to one embodiment.

## DETAILED DESCRIPTION

Various embodiments disclosed herein relate to methods and devices for treating a syndesmosis injury, such as, for example, an ankle syndesmosis injury. More specifically, various embodiments herein relate to syndesmosis injury treatments using tension or connection systems and methods for anchoring or otherwise coupling bones such as the tibia and fibula bones. Some of the various device and method embodiments disclosed herein operate at least in part by anchoring or coupling to the tibia and fibula bones. While various embodiments as described herein relate to the ankle syndesmosis joint, it is understood that the embodiments can also apply to other syndesmosis joints in the body, including those existing in the wrist, forearm, spine and shoulder.

Various prior art screws are too rigid for permanent implantation and thus are often removed. Other prior art devices (such as, for example, the Tight Rope™ system available from Arthrex) can be flexible enough that removal is not required, but are not secure enough during the acute healing phase to provide optimal healing. In contrast, certain of the implant embodiments described and/or contemplated herein can remain in the patient's body permanently. Some embodiments provide substantially secure fixation during the healing period but do not cause long-term binding of the joint. Other embodiments provide an implanted fixation system that is either flush with, or internal to, the cortical bone. Certain implementations also allow the surgeon to adjust the spacing between the tibia and fibula after implantation. As such, various embodiments disclosed herein provide systems and methods for implantation of treatment devices and treatment of ankle syndesmosis injuries with reduced trauma and quicker recovery in comparison to known systems and treatments.

One embodiment of a syndesmosis repair device **10** is depicted in FIG. **2**. In this embodiment, the device or system **10** couples the tibia **2** and fibula **4** bones of a human leg. As shown in the figure, the device **10** is an implant having a first anchor **12** positioned in the tibia **2**, a second anchor **14** positioned in the fibula **4**, and a tether **16** coupled to or coupling the first anchor **12** to the second anchor **14**. According to the specific implementation in FIG. **2**, the first anchor **12** is an externally threaded anchor **12** embedded in the tibia **2** and the second anchor **14** is an internally threaded anchor threadably coupled to the tether **16** and positioned within a countersunk hole **18** drilled in the fibula **4**. As best shown in FIG. **5**A in combination with FIG. **2**, the tether **16** in this implementation has a flexible component **16**A and a cylindrical base component **16**B, wherein the flexible component **16**A is at least one suture **16**A coupled to the first anchor **12** and the cylindrical base component **16**B at one end is coupled to the at least one suture **16**A and at the other end is threadably coupled to the second anchor **14**.

In this embodiment, the anchors **12**, **14** are strategically embedded within the tibia **2** and fibular to urge the two bones together, thereby correcting or otherwise treating an ankle syndesmosis injury. Alternatively, it is understood that the anchors **12**, **14** can be positioned anywhere along any two bones to treat a syndesmosis injury. Further, as discussed above, in the depicted embodiment the first anchor **12** is an externally threaded bone anchor **12** and the second anchor **14** is an internally-threaded bone anchor **14**. Alternatively, the anchors **12**, **14** can take a variety of different forms as contemplated herein, including several discussed below, without departing from the spirit of the invention. In addition, as noted above, the implementation as shown in FIG. **2** and FIG. **5**A includes a tether **16** having a flexible component **16**A comprised of at least one suture **16**A and a cylindrical base component **16**B. Alternatively, the tether **16** can take a variety of known forms.

It is understood that each of the various device and method embodiments disclosed herein can be the sole treatment for the syndesmosis injury. It is further understood that any of these embodiments could also be used in conjunction with any one or more of other known treatments, such as plates and/or screws associated with bone fracture(s).

It is understood that the term "bone anchor" (or, alternatively, "anchor"), as used herein, is intended for purposes of this application to mean any component or device that can be used with any of the treatment device embodiments disclosed herein for anchoring or coupling such treatment devices to a bone. It is also understood that "tether," as used herein, is intended to mean any elongate component for use with medical devices such as suture, thread, a tube, or any other such material or device or combination thereof that can couple or be tensioned between two components such as anchors to treat syndesmosis injuries. In addition, it is understood that "prong," as used herein, is intended for purposes of this application to mean any component or device that projects or extends from a bone anchor and is intended to enhance fixation of the anchor in the bone.

One embodiment of a first anchor **12** is depicted in FIGS. **3**A-**3**C. In this implementation, the anchor **12** has external threads **30** and a tip **32** at the distal end of the anchor **12** to facilitate threaded insertion into the tibia **2**. At the proximal end **34** (as best shown in FIGS. **3**B and **3**C), the anchor has a set of slots **36** that are configured to receive projections of an implantation tool as described in further detail below. In this embodiment, the proximal end **34** of the anchor **12** has three slots **36** defined in the threads **30**. Alternatively, the anchor **12** can have any number of slots **36** for use in coupling with an implantation tool. In accordance with one implementation, the slots **36** are defined in the threads **30** as shown such that the implantation tool (as described below) can couple with the anchor **12** without requiring a coupling component disposed within the lumen **38** of the anchor **12** or requiring any type of coupling component that extends proximally or radially from the anchor **12**. As such, these slots **36** defined within the threads **30** allow the lumen **38** to be free to be utilized for other purposes/functions, and also minimizes the profile of the anchor **12** both radially and proximally. In a further alternative, the anchor **12** can have any coupling structure or feature at the proximal end **34** that allows for coupling with an implantation tool.

In accordance with one implementation, the first anchor **12** has threads configured the same as a standard metallic cortical or cancellous bone screw **12**. In another embodiment, the implantation tool is featured to drive the screw into the bone via fingers or protrusions **146** from an annular space between the major and minor diameters of the threads and at a distance distal to the proximal aspect of the screw. This embodiment allows the anchor to engage the lateral cortical aspect of the tibia while presenting a smooth profile on the lateral bone

surface and allows complete circumferential thread engagement right up to the lateral bone surface.

Alternatively, the first anchor **12** can be any known type of anchor, including, for example, a screw, an expandable anchor, or an external button. In one exemplary alternative embodiment as depicted in FIG. **4**, the first anchor **12** is a pronged anchor **12**. In this implementation, the anchor **12** has prongs **50** that extend out from the anchor **12** into the bone to facilitate fixation of the anchor **12** in the bone.

It is understood that certain embodiments of the first anchor **12** are substantially rigid and are configured to be capable of cutting bone (e.g. self-tapping threads). Additionally, various embodiments of the first anchor **12** can also have radiopacity or radiolucency. It is also understood that the first anchor **12** material must be biocompatible.

It is further understood that any of the first anchor embodiments contemplated herein, or portions thereof, can be made of any suitable material, including plastically deformable materials, biocompatible polymers, relatively rigid polymeric materials, or metals. Specific examples can include stainless steel, MP35N, titanium and titanium alloys, nitinol, plastic, UHMWPE, cross-linked UHMWPE, PEEK, polycarbonate, polylactic acid (PLLA or PDLA), bone allograft, hydoxyapatite coral coated for ingrowth, human dermis, porcine intestinal mucosa, fetal bovine skin, porcine skin, cadaveric fascia, marlex mesh, hernia mesh, polytetrafluorethylene, absorbable suture, or umbilical tape. According to one embodiment, a first anchor **12** having prongs is formed of commercially pure titanium.

These various characteristics and any other alternative characteristics discussed above or elsewhere with respect to various first anchor **12** embodiments can apply to any of the anchors **12** described with respect to any of the device embodiments described or contemplated herein.

A tether **16** in accordance with one implementation is depicted in FIGS. **5**A-**5**D. The tether **16** has a flexible component **16**A and a base component **16**B. The flexible component **16**A embodiment depicted in FIGS. **5**B-E is a suture **16**A coupled at the distal end to the first anchor **12** and at the proximal end to the base component **16**B. In one embodiment as best shown in FIG. **5**C, the single suture **16**A is tied together at knot **46** and formed into a single loop **16**A.

As best shown in FIGS. **5**C, **5**D, and **5**E, the suture **16**A comprises a single line having two loops coupled to the distal end of the base component **16**B. More specifically, the loops of the suture **16**A are threaded through two holes **42** at the distal end of the base component **16**B and looped around a portion of the circumference of the base component **16**B in a groove **44** and threaded back through the other of the two holes **42**. As best shown in FIGS. **5**D and **5**E, the two holes **42** are directly below and orthogonal to the groove **44** in the base component **16**B. In one embodiment, these holes **42** are in this location to maximize the load bearing capacity of the base component **16**B. The suture **16**A places a load on the base component **16**B when the implant is placed in tension from natural physiologic motion. The positioning of the holes **42** as shown in FIG. **5**D can maximize the capacity of the base component **16**B to withstand that load. In accordance with one embodiment, the maximum load capacity of the groove **44** at the distal end of the base component **16**B is 75 lbs. Alternatively, the maximum load capacity can be any amount between 0 and 75 lbs. In one implementation, the load capacity is directly proportional to the size of the cross-sectional area of the base component **16**B. According to one embodiment, the distal end of the base component **16**B can be configured to have a maximum load capacity with a predetermined failure point based on the materials and specific dimensions selected for the base component **16**B.

As best shown in FIGS. **5**B and **5**C, the suture **16**A also has two loops coupled to the proximal end of the first anchor **12**. More specifically, the loops of the suture **16**A are threaded around a cross pin **40** within the lumen **38** at the proximal end of the first anchor **12**.

According to one method of making the device, the suture **16**A is coupled to or threaded onto the base component **16**B and then the suture **16**A is tied together with the knot **46**. In accordance with one alternative embodiment, the cross pin **40** can be removably positioned in one of several different holes (not shown) spaced along the interior of the lumen **38** of the first anchor **12**, thereby allowing for adjustment of the positioning of the pin **40** to adjust the overall distance between the anchor **12** and the base component **16**B. In addition, the adjustment capability of the pin **40** eliminates any slack in the suture **16**A resulting from the need for the user to tie the suture **16**A together with the knot **46**.

In one embodiment, the distance between the anchor **12** and the base component **16**B should range from about 0.050 inches to about 0.150 inches. Alternatively, the distance can be any amount that results in the desired positioning of the tibia **2** and fibula **4** as discussed elsewhere herein.

Alternatively, the loops of the suture **16**A can be threaded around or through any type of projection or similar feature on the anchor **12**. In a further alternative, the flexible component **16**A can be coupled to the base component **16**B and the first anchor **12** in any known fashion.

According to another alternative embodiment, the flexible component **16**A can be connected to the first anchor **12** such that there is no knotting. One such embodiment is shown in FIGS. **5**F and **5**G, which depict a plug **52** that can be used in combination with the flexible component **16**A and the first anchor **12** to attach the flexible component **16**A to the first anchor **12**. The plug **52** has grooves **54** defined on opposite sides of the plug **52**, and the grooves **54** have projections **56** in the walls of the grooves **54**. The plug **52** is configured to be positionable within the lumen **38** at the proximal end of the first anchor **12**. As best shown in FIG. **5**G, the flexible component **16**A of the tether **16** can be coupled to the first anchor **12** by positioning the sutures **16**A within the grooves **54**. According to certain embodiments, the projections **56** in the grooves **54** urge the strands of the suture **16**A contained therein against the internal surface of the lumen **38**, thereby creating a tension or frictional fit that retains the suture **16**A in place and thus results in the attachment of the suture **16**A to the first anchor **12**. In accordance with one implementation, this plug **52** can be used with a flexible component **16**A comprising multiple sutures **16**A or strands of sutures **16**A. Alternatively, it can also be used with a single stranded suture **16**A or any other type of suture-like flexible component **16**A. In one embodiment, this implementation can allow flexibility during assembly in establishing the separation distance between the first anchor **12** and the tether **16**.

According to an alternative implementation, the flexible component **16**A can be a set of multiple (e.g., four) separate suture lines, each of which is individually coupled to the first anchor **12** and the tether base **16**B. In a further alternative, the flexible component **16**A can be one suture, two sutures, three sutures, four sutures, or more than four sutures. In yet another alternative, the flexible component **16**A can be any known flexible component or material and can be coupled to the cylindrical base component **16**B in any known fashion using any known coupling components or methods.

In one alternative implementation, the flexible component **16**A can have a predetermined failure point such that it will

fail at some predetermined amount of applied force that is lower than the anticipated anchoring force of the first anchor **12** in the tibia **2** or the second anchor **14** in the fibula **4**. For example, if the expected anchoring forces of the first anchor **12** and second anchor **14** are 60 pounds, the flexible component **16**A can be designed to break at a lower force, such as, for example, 50 pounds. As such, if the device is exposed to an unusually high biomechanical force, such as an unexpected fall by the patient, the flexible component **16**A in this embodiment is designed to fail before the high force causes the first anchor **12** or second anchor **14** to be pulled from their respective implantation sites. Although the result is a failure of the tether **16**, it is understood that it is easier to repair the failed tether **16** rather than repair the substantial damage resulting from an anchor being pulled out of the bone.

In yet another alternative, the flexible component **16**A can be any number of individual pieces of a variety of suitable implantable materials. Such materials include monofilament or multi-filament structures such as yarns, braids, or weaves. In accordance with one embodiment, the tether has lateral flexibility, and as such, materials that could provide lateral flexibility include polyester (such as Dacron™), ultra-high molecular weight polyethylene (UHMWPE), high strength expanded PTFE, or polycarbonate urethane. Other materials include those exhibiting higher elasticity, such as silicone, silicone rubber, PEBA such as Pebax™, Kraton™ polymers, polyurethane, latex, or any other elastomeric materials. In certain embodiments, the flexible component **16**A is made of any flexible but non-bio-absorbable material, thereby providing long-term syndesmotic joint reduction without reducing flexibility. In other implementations, the tether embodiments can be made of a bio-absorbable material such as polylactic acid, poly-L-lactic acid, PLGA, or any known bioabsorbable material such as those used in biodegradable sutures. The bio-absorbable materials can allow for short term flexibility while being absorbed over some predetermined period of time such that the tether **16** ultimately fractures in a controlled and predetermined fashion. It is understood that various combinations of the above materials are also contemplated.

As shown in FIG. **5**A, the base component **16**B in this embodiment has a threaded portion **68** with external threads **70** extending from the distal end of the component **16**B to some point along the length of the component **16**B. The threaded portion **68** is configured to engage with the threaded lumen **84** of the second anchor **14** as described in further detail below, and the non-threaded portion **72** extends proximally from the threaded portion **68**. In an alternative embodiment, the distal portion of the component **16**B can have any other known mechanism for engaging with the second anchor **14** instead of threads. In various embodiments, the base component **16**B is substantially rigid. In further embodiments, the base component **16**B is made of a material that can be trimmed or cut as described elsewhere herein. In one embodiment, the tether base component **16**B is comprised of polyether ether ketone ("PEEK"). Alternatively, the component **16**B can be made of any suitable biocompatible material, such as stainless steel, titanium, cobalt alloy, polyester, PTFE, nylon, HDPE, or the like. In a further implementation, the base component **16**B can be made of a flexible material, thereby resulting in greater flexibility and angular rotational freedom for the overall construct. In one implementation, a base component **16**B made of flexible material allows the surgeon to tailor the system flexibility to the needs of the patient, because, for example, different patients can exhibit different levels of baseline fibula rotation.

In the embodiment as shown, the base component **16**B is a cylindrical base component **16**B. Further, in this embodiment, the cylindrical base component **16**B is also a tubular base component **16**B, meaning that it has a lumen **156** defined within the component **16**B, as best shown in FIG. **12**E. Alternatively, the cylindrical base component **16**B has no lumen. In a further alternative, the base component **16**B can have any configuration that allows for use in an implantable device as contemplated herein.

In further implementations, either or both of the flexible component **16**A or base component **16**B can have radiopacity or radiolucency. Further, either or both of the components **16**A, **16**B can be made of fatigue resistance materials.

Alternatively, instead of two components **16**A, **16**B, the tether **16** can be a single component. In one exemplary embodiment of a single component tether **16** or a tether **16** having no flexibility portion, the tether **16** has fracture notch or point (not shown) that can be intentionally fractured by a user or physician at some desired time. In one embodiment, the fracture notch or point can be fractured by the application of controlled torsion to the lateral aspect of the implanted tether **16** by a user or physician. For example, the fracture notch or point can be fractured after a successful soft tissue healing period. Alternatively, any known fracture structure or method can be used.

In a further alternative, the tether **16** can be any known elongate device or structure for coupling two bone anchors. In one implementation, the tether can be any tether or tether material—or variations thereof—as described in U.S. application Ser. No. 12/371,354, filed on Feb. 13, 2009 and entitled "Methods and Devices for Treating Hallux Valgus;" U.S. application Ser. No. 12/567,314, filed on Sep. 25, 2009 and entitled "Methods and Devices for Treating A Structural Bone and Joint Deformity;" U.S. application Ser. No. 12/691,646, filed on Jan. 21, 2010 and entitled "Methods and Devices for Treating Hallux Valgus;" or U.S. application Ser. No. 12/793,429, filed on Jun. 3, 2010 and entitled "Methods and Devices for Treating Hallux Valgus," each of which is hereby incorporated herein by reference in its entirety.

To further achieve short term rigidity and long term flexibility, various tether embodiments contemplated herein can incorporate a combination of rigid and bio-absorbable or rigid and flexible components, wherein the various combinations can be intended to change rigidity over time or designed to fracture in a controlled fashion.

It is further understood that any tether embodiment described throughout this application can be configured according to any of the configurations or materials described above or elsewhere herein.

A second anchor **14** according to one embodiment is depicted in FIGS. **6**A and **6**B. The anchor has a head **80** at the proximal end of a body **82**. The tubular body **82** has a lumen **84** defined through the length of the body **82** and through the head **80**. An opening **86** to the lumen **84** is defined in the head **80** and an opening **88** to the lumen **84** is defined in the body **82**. The lumen **84** has internal threads **90** configured to be threadably engageable with the external threads **70** of the tubular base component **16**B of the tether **16**. Alternatively, the anchor body **82** is attached to the fibula **4** by any known attachment method, material, or device, such as, for example, a porous outside surface that facilitates bony in-growth. Additionally, the body **82** can also have any known mechanism for engaging with the tether base component **16**B.

In one embodiment, the second anchor **14** is configured to be positioned against or adjacent to the surface of the lateral aspect of the fibula **4**, as described in further detail below. In certain alternative implementations, the anchor **14** can be configured to couple with, interface with, or otherwise be associated with a fracture fixation plate positioned against the

lateral aspect of the fibula **4**. Alternatively, the anchor **14** is configured to be positioned in a countersink hole or counterbore hole as described in further detail below. In yet another alternative, the anchor **14** is configured to have a low profile such that it can be positioned against the fibula without a countersink hole. For example, the anchor **14** can be thin, can have a rounded head, or can otherwise have a low profile. In a further implementation, the anchor **14** can be made of a flexible material, thereby resulting in greater flexibility and angular rotational freedom for the overall construct. In one implementation, an anchor **14** made of flexible material allows the surgeon to tailor the system flexibility to the needs of the patient, because, for example, different patients can exhibit different levels of baseline fibula rotation.

In this embodiment, the head **80** has four slots **92** defined in the head **80** that are configured to couple with a driver tool, such as the driver tool **160** discussed below, by receiving projections on the driver tool such as the driver tool **160** as described in further detail below. It is understood that, while depicted in a particular configuration in FIGS. **6**A and **6**B, the four slots or holes **92** can be defined in the head **80** in any known shape, configuration, or position on the head **80**. Alternatively, any number of holes **92** can be defined in the head **80**. In a further alternative, the second anchor **14** can have any structure or feature that can be used to couple with a driver tool. In a further alternative, the second anchor **14** can be the same as or similar to the threaded bone anchor embodiments disclosed in U.S. application Ser. No. 12/691,646 or 12/567,314, both of which are incorporated by reference above. It is understood that any of the second bone anchor embodiments contemplated herein can be made of any known material that is suitable for implantable medical components or devices. According to certain implementations, the second anchor **14** is substantially rigid. In one embodiment, the second bone anchor can be made of a relatively rigid material such as stainless steel, titanium, a rigid polymer such as PEEK, or the like. In further implementations, the anchor **14** can have radiopacity or radiolucency.

Various alternative embodiments of the second anchor **14** are depicted in FIGS. **6**C-**6**E. Each of these implementations has a head **80** with a different configuration. For example, the second anchor **14** embodiment in FIG. **6**C has a head **80** with a substantially straight, angled wall **94** between the top of the head **80** and the body **82**. This anchor **14** can be used with a countersink hole formed in the bone as described elsewhere herein, resulting in the anchor **14** having a "zero profile" (i.e., being sunk flush into the bone). That is, the angled wall **94** is configured to fit within a countersink hole. In contrast, the second anchor **14** embodiment depicted in FIG. **6**D has a head **80** with a rounded wall **96** between the top of the head **80** and the body **82**. This anchor **14** can be used with a standard fixation plate, which has correspondingly rounded holes configured to receive various standard screws. The third embodiment of a second anchor **14** is shown in FIG. **6**E. In this implementation, the top **98** of the head **80** is rounded. The rounded head **80** has a minimal profile with an optimal footprint, and thus can be used when there is no countersink, counterbore, or fixation plate.

Various implantation methods, systems, and devices can be used to implant treatment devices similar to those depicted in FIGS. **2**-**6**B. In accordance with one embodiment, a treatment device can be implanted in the following manner.

First, as shown in FIG. **7**, a guidewire **100** is inserted through the fibula **4** and into the tibia **2**. In one embodiment, the guidewire **100** is 304 Stainless Steel, which is commercially available from Orthomed. In certain embodiments, the guidewire **100** can also be known as a "K-wire."

The guidewire can be positioned in the bones **2**, **4** using any known procedure. Alternatively, the procedure set forth in FIGS. **8**A-**8**D can be used, especially in those situations in which the fibula **4** has been fractured. First, as shown in FIG. **8**A, a plate **110** is positioned along the fibula **4** at the point of fracture. The plate **110** according to one implementation has multiple holes **112** defined through the plate **110**.

Once the plate **110** is positioned correctly/as desired, one or more bone anchors or screws **114** are inserted through one or more of the holes **112** and embedded into the bone **4**, as shown in FIG. **8**B. In this embodiment, four anchors **114** are inserted through four holes **112**. Alternatively, any number of any known type of fixation components can be used. These anchors **114** secure the plate **110** against the bone **4** and thereby stabilize the fracture.

Once the plate **110** is secured, a wire guide **116** can be inserted into the remaining hole **112**, as shown in FIG. **8**C. The wire guide **116** is any known guide for guiding insertion of a guidewire (such as, for example, a K wire or any other known guidewire) through the guide **116** and the plate **110** and into the bone **4**. The wire guide **116** has a lumen **118** defined through the length of the guide **116** that is configured to receive the guidewire.

When the wire guide **116** is in place, the guidewire **100** is inserted through the lumen **118** in the wire guide **116** and into the bone **4**. In one embodiment, the guidewire **100** is inserted through the fibula **4** and into the tibia **2**.

Referring again to implantation steps when a plate **110** is not utilized, once the guidewire is in place, as shown in FIG. **9**, a drill **130** having a lumen (not shown) defined through the length of the drill **130** is positioned over the guidewire **100** and used to drill a hole through the fibula **4** and into the tibia **2**, using the guidewire **100** as a guide. The drill **130** has a drill bit **132** that has a countersink component **134** at the proximal end of the bit **132**. The countersink component **134** is a portion of the drill bit **132** having a larger diameter than the rest of the bit **132**, thereby being able to form a countersink hole portion near the surface of the fibula bone **4** that is wider than the rest of the hole. One example of the resulting hole **136** with the countersink hole **138** at or near the surface of the bone **4** is depicted in FIG. **10**. The countersink hole **138** allows the second anchor **14** to be countersunk into the bone **4** as subsequently depicted in FIGS. **20**-**22**. Alternatively, the drill bit **132** has a counterbore component that forms a counterbore hole at or near the surface of the bone, wherein the counterbore has flat sides instead of the angled sides of a countersink hole.

Once the hole **136** has been drilled, an implantation tool **140** (also referred to herein as a "deployment tool") is used to position the first anchor **12** and the tether **16** in the tibia **2** and the fibula **4**. That is, as shown in FIG. **11**, the tool **140** with the first anchor **12** attached to the distal end of the tool **140** is inserted into the hole **136** such that the first anchor **12** is positioned in the tibia **2**. In one embodiment, the hole in the tibia **2** has a diameter that is less than the diameter of the threads **30** on the first anchor **12**, thereby requiring that the first anchor **12** be urged into the hole **136** in the tibia **2** by rotating the tool **140** and thereby rotating the first anchor **12** and urging it into the hole **136**.

The implantation tool **140**, according to one embodiment, is depicted in further detail in FIGS. **12**A-F. The tool **140** has a tool body **142** with a distal end **144** having three prongs **146** as best shown in FIG. **12**D. The distal end **144** with the three prongs **146** further defines an opening **148** in fluid communication with a lumen **150** that is defined within the tool body **142** and runs along the entire length of the tool body **142**. The tool **140** also has a handle **152** coupled at the proximal end

154 of the tool body 142. In certain embodiments, the tool 140 is a substantially rigid tool having the ability to transmit torque to the anchor 12. For example, the tool body 142 can be made of stainless steel or any other known material for use in a driving tool for implantable medical devices. In a further example, the handle 152 can be made of polycarbonate or any other known material for use in a driving tool for implantable medical devices.

As mentioned above, prior to implantation, the distal end 144 of the tool body 142 is coupled to the proximal end 34 of the first anchor 12 as best shown in FIGS. 12A-12C. That is, the three prongs 146 are configured to be engageable with the slots 36 defined in the proximal end of the anchor 12. The slots 36 are described in further detail above with respect to FIGS. 3A-3C. FIGS. 12A-12C depict the tool 140 coupled to the anchor 12.

As best shown in FIGS. 12B, 12E, and 12F, prior to implantation, the tool 140 also contains the tether 16. That is, prior to implantation, the tether 16 is disposed within the lumen 150 of the tool body 142 and coupled to the first anchor 12. The flexible component 16A in this embodiment consists of a suture 16A that is coupled at a distal end to the first anchor 12 and at a proximal end to the tubular base component 16B as described in detail above. The tubular base component 16B is disposed within the lumen 150 of the tool body 142.

Upon placement of the first anchor 12 to the desired depth in the tibia 2 as discussed above (such as, for example, the proximal end of the anchor 12 being flush or substantially flush with the surface of the tibia 2 with the threads of the anchor 12 engaging the cortex), the implantation tool 140 is retracted as shown in FIG. 13, leaving the first anchor 12 implanted in the tibia 2 and the tether 16 coupled to the first anchor 12 and disposed through the hole in the fibula 4 as best shown in FIG. 14.

Once the implantation tool 140 is retracted, the second anchor 14 can be positioned over and attached to the tether 16. The second anchor 14 is depicted in FIGS. 6A and 6B and described in detail above.

In one embodiment, the second anchor 14 can be coupled to the tether 16 using a driver tool 160 as shown in FIGS. 15A-15B. In this implementation, the driver tool 160 has a tubular body 162 and a head 164, along with a lumen 166 defined through the length of the body 162 and through the head 164. The distal end of the body 162 has four prongs 168 configured to be engageable with the anchor 14. In certain embodiments, the tool 160 is a substantially rigid tool having the ability to transmit torque to the anchor 14. For example, the tool 160 can be made of stainless steel, polycarbonate, or any other known material for use in a driving tool for implantable medical devices. In an alternative implementation, the driver tool 160 incorporates an internal clutch 170 to assist in safe and desired placement of the anchor 14. The internal clutch 170 is comprised of a clutch plate 172, an adjustable spring (or springs, as shown) 174 and a retainer clip 176. The clutch 170 pressure is affected by the adjustable spring(s) 174. As the clutch pressure increases, the clutch plate 172 allows the surgeon to place more torque on the anchor 14 before the clutch "slips" and prohibits further increases in torque.

In use, the driver tool 160 is engaged with the second anchor 14 by inserting the prongs 168 into the holes 92 defined in the head 80 of the anchor 14. The anchor 14 and tool 160 are then inserted over the tubular base component 16B of the tether as best shown in FIGS. 16A and 16B. As the anchor 14 is advanced distally along the base component 16B, the anchor 14 eventually reaches the threads 70 on the base component 16B. According to one embodiment, the external diameter of the threads 70 on the base component 16B and the diameter of the internal threads 90 in the lumen 84 of the anchor are sized such that the threads 90 in the lumen 84 are engageable with the threads 70 on the base component 16B. As such, when the anchor 14 comes into contact with the threads 70 on the base component 16B, the user must start rotating the head 164 of the driver tool 160 to continue to advance the anchor 14 distally along the base component 16B. The anchor 14 is advanced until it reaches the desirable position with respect to the fibula 4. In one implementation, the anchor 14 is in the desired position when it is in contact with the fibula 4 and has urged the fibula 4 to the desired position with respect to the tibia 2, thereby treating the syndesmosis injury. One advantage of this embodiment is the ability to adjustably position the fibula 4 with respect to the tibia 2 to any desired position.

In one implementation, the "desired position" of the fibula 4 with respect to the tibia 2 is clinically measured by the medial clear space and the overlap of the tibia and fibula. According to one embodiment, this measurement can be accomplished by viewing the positions of the tibia 2 and fibula with any known technology for viewing bones in a patient. In one specific exemplary implementation, the positions of the bones can be analyzed using radiography. For example, an anterior-posterior or mortise view can be captured using radiographic equipment. It is understood that, according to one embodiment, the medial clear space on an anterior-posterior radiograph should be less than 5 mm and the overlap of the tibia and fibula should be less than 1 mm on the mortise view radiograph, as disclosed in Cottom, et al., "Treatment of Syndesmotic Disruptions with the Arthrex Tightrope: A Report of 25 Cases," *Foot and Ankle International*, Vol. 29, No. 8, pp. 773-780 (2008), which is hereby incorporated herein by reference in its entirety.

In an alternative embodiment, the "desired position" of the fibula 4 with respect to the tibia 2 can be determined by evaluating ankle function. That is, a surgeon can use ankle function as a proxy for appropriate "bony relationships" such as the relative positions of the tibia 2 and fibula 4. One such evaluation method is described in Peter, et al., "Biomechanical Effects of Internal Fixation of the Distal Tibiofibular Syndesmotic Joint: Comparison of Two Fixation Techniques," *Journal of Orthopedic Trauma*, Vol. 8, No. 3, pp. 215-219 (1994), which is hereby incorporated herein by reference in its entirety.

As such, in accordance with various embodiments, a surgeon or physician or other appropriate caregiver can initially position the second anchor 14 as described above, evaluate the relative position of the fibula 4 with respect to the tibia 2, and then re-position the anchor 14 to achieve the desired positioning.

Once the anchor 14 has been positioned as desired, the driver tool 160 is removed, as best shown in FIG. 17. Upon removal of the tool 160, a portion of the base component 16B extends proximally from the anchor 14. According to one embodiment, the portion of the component 16B extending proximally from the anchor 14 can be removed.

FIG. 18 depicts one implementation of a cutting tool 180 for removing the portion of the base component 16B extending proximally from the anchor 14. As shown in FIG. 18, the cutting tool 180 has a first arm 182 and a second arm 184 that are coupled to each other at the proximal end 186 and each have a rounded cutting edge 188, 190 at their distal ends. Alternatively, it is understood that the cutting surfaces 188, 190 of the tool 180 can take any form that allow for cutting the tether. The tool 180 also has an actuation arm 192 that is operably coupled to the first arm 182. The two arms 182, 184

are moveable in relation to each other by actuating the actuation arm **192**, thereby causing the two cutting edges **188**, **190** to move in relation to each other in an arcuate path as shown with reference letter "P."

In use, the tool **180** can be used to sever or otherwise remove the excess tether at a desired point such that the tether **16** does not extend beyond the proximal end of the second anchor **14**. When the actuation arm **192** is actuated downward (in relation to the device **180**, the two cutting surfaces **188**, **190** move toward each other in the arcuate path P as described above. According to one embodiment, the arcuate path P combined with the rounded cutting surfaces **188**, **190** enable the cut surface of the base component **16**B to be at the outer surface of anchor **14** or at some point that is positioned within the hole in the bone (rather than external to the bone such that the tether **16**B is projecting from the bone). Alternatively, any known cutting device or system can be used.

In use, as shown in FIG. **19**, the cutting tool **180** can be positioned over the base component **16**B by moving the tool **180** distally over the component **16**B until the tool **180** is adjacent to or in contact with the anchor **14**. One the tool **180** is positioned as desired, the tool **180** can be actuated to cut the base component **16**B, thereby resulting in an implanted device **10** as best shown in FIG. **20**. In one implementation, the base component **16**B embodiment having a lumen **156** is easier to cut than an embodiment without a lumen.

As discussed above, one advantage of various embodiments disclosed herein is the ability to adjust the tension of the device **10**, thereby resulting in the adjustment of the distance between the tibia **2** and the fibula **4**. This adjustment capability is shown in FIGS. **20** and **21**. FIG. **20** shows the device **10** implanted such that there is a gap between the tibia **2** and fibula **4**. If it is desirable to reduce that gap, the second anchor **14** can be rotated to reduce the length of the tether **16**, thereby urging the tibia **2** and fibula **4** closer together and reducing the gap between them as shown in FIG. **21**.

An alternative device **200** is depicted in FIG. **22**. This device has a first anchor **12** that is a pronged anchor **12** similar to that shown in FIG. **4** above. In this embodiment, the first anchor **12** can be deployed in the tibia **2** by any known method of deploying a pronged anchor. According to one implementation, the pronged anchor **12** can be deployed using methods similar to those disclosed in U.S. application Ser. No. 12/793,429, discussed and incorporated by reference above.

One exemplary embodiment of the device **200** and implantation tool **220** and the related methods for implanting the device **200** (as shown in FIG. **22**) are depicted in further detail in FIGS. **23**A-**23**F. As best shown in FIGS. **22**, **23**A, and **23**B, the device **200** has an expandable pronged first anchor **12**, a tether **16**, and a second anchor **14**. In some embodiments, the pronged first anchor **12** can be similar to the anchor **12** depicted in FIG. **4**. The first anchor **12** is coupled to the tether **16**. The tether **16** has a non-threaded component **202**A and a threaded component **202**B. In one embodiment, the non-threaded component **202**A is a flexible component **202**A. Alternatively, the non-threaded component **20**A can be a substantially rigid component **202**A.

The tool **220** has a tool body **222** with a distal end **224** having prongs **226** as best shown in FIG. **12**C. The distal end **224** with the prongs **226** further defines an opening (not shown) in fluid communication with a lumen **228** (as best shown in FIG. **23**A) that is defined within the tool body **222** and runs along the entire length of the tool body **222**. The tool **220** also has a handle **230** coupled at the proximal end of the tool body **222**.

Prior to implantation, the distal end **224** of the tool body **222** is coupled to the proximal end of the first anchor **12** as best shown in FIG. **23**D. That is, the prongs **226** are configured to be engageable with the anchor **12**. As best shown in FIGS. **23**A-**23**C, prior to implantation, the tool **220** also contains the tether **16**. That is, prior to implantation, the tether **16** is disposed within the lumen **228** of the tool body **222** and coupled to the first anchor **12**. In addition, prior to implantation, a deployment component **232** is disposed through a lumen in the first anchor **12** and tether **16**. The deployment component **232** has a deployment anvil **234** at the distal end of the deployment component **232**. According to one embodiment, the deployment component can be used to "deploy" the pronged first anchor **12**, urging the anchor **12** from the undeployed to the deployed configuration.

According to one embodiment, the device **200** can be implanted by positioning the first anchor **12** through the fibula **4** and to the desired depth in the tibia **2** with the implantation tool **220**, as best shown in FIG. **23**D. Upon placement of the first anchor **12** to the desired depth, the implantation tool **220** is retracted as shown in FIG. **23**E, leaving the first anchor **12** implanted in the tibia **2** and the tether **16** coupled to the first anchor **12** and disposed through the hole in the fibula **4**. At this point, the deployment component **232** is still disposed through the first anchor **12** and tether **16** and extends proximally from the tether **16**. To deploy the anchor **12**, the user can pull the deployment component **232** proximally in relation to the anchor **12** and tether **16**, either manually or using a deployment tool (not shown) similar to that disclosed in U.S. application Ser. No. 12/793,429, discussed and incorporated by reference above. Urging the device **232** in the proximal direction urges the anvil **234** in the proximal direction, thereby forcing the prongs of the first anchor **12** into the deployed configuration in a fashion similar to that disclosed in U.S. application Ser. No. 12/793,429. In addition, according to certain embodiments, when the prongs reach the fully deployed configuration, further pulling of the device **232** causes a designed fracture point (not shown) on the device **232** to exceed its maximum tolerance, thereby causing the tool **232** to fracture, allowing the user to remove the device **232** while only the anvil **234** remains in the device **200**.

Once the implantation tool **220** is retracted and the first anchor **12** is deployed, the second anchor **14** can be positioned over and attached to the tether **16**, as best shown in FIG. **23**F. The second anchor **14** can be an anchor **14** such as those depicted in FIGS. **6**A and **6**B and described in detail above. In one embodiment, the second anchor **14** can be coupled to the tether **16** using a driver tool **236** as shown in FIG. **23**F. The driver tool **236** can be similar to the driver tool **160** described above. In use, the anchor **14** and tool **236** are inserted over the tether **16** and the anchor **14** is advanced distally along the tether **16** until the anchor **14** reaches the threads **202**B on the tether **16**. When the anchor **14** comes into contact with the threads **202**B on the tether **16**, the user rotates the driver tool **236** to continue to advance the anchor **14** distally along the tether **16**. The anchor **14** is advanced until it reaches the desirable position with respect to the fibula **4**.

Once the anchor **14** has been positioned as desired, the driver tool **236** is removed, as best shown in FIG. **23**F. In some embodiments, upon removal of the tool **236**, a portion of the tether **16** extends proximally from the anchor **14**. According to one embodiment, that portion can be removed using a cutting tool (not shown) similar to the tool depicted in FIG. **18** using similar methods. Once the excess portion of the tether **16** is removed, the device **200** is fully implanted as shown best in FIG. **22**.

In one implementation, at least a portion of the tether **16** in the device **200** is made of bio-absorbable material. For example, according to one embodiment, the bio-absorbable

portion of the tether **16** is the portion that spans the syndesmotic gap between the tibia **2** and the fibula **4**. In such an embodiment, the bio-absorbable portion of the tether **16** would provide substantially rigid or semi-rigid fixation during the healing period but enhance flexibility after healing was complete, because the bio-absorbable portion would ultimately be absorbed.

In a further alternative embodiment, the device **200** has a flexible tether **16**. More specifically, the tether **16** can be made of a flexible material, such as, for example, a flexible polymeric material. In certain implementations, the tether **16** can be a solid flexible polymer, a combination of several smaller flexible elements, a series of suture lines, or any other known flexible configuration. It is further understood that the tether **16** in the device **200** can be any tether configuration or material as described throughout this application.

According to a further alternative embodiment as shown in FIG. **24**, the device **200** (or any other implantable device contemplated herein) can be implanted using a fracture fixation plate **250**. It is further understood that various embodiments disclosed and contemplated herein can be used with any known fixation device positioned along either the tibia **2** or fibula **4** or both for purposes of stabilizing the bone(s).

In another alternative implementation, the device **200** can be implanted through the tibia **2** and into the fibula **4**, as best shown in FIG. **25** (in a "reverse orientation" in contrast to implantation through the fibula **4** and into the tibia, which is described in detail above and elsewhere herein). It is further understood that the various methods and devices described herein can be used to implant any device contemplated herein in such a reverse orientation. According to certain embodiments, the reverse orientation can result in no protrusion on the fibula **4** (in comparison to the other embodiments described above) or can be employed when there is no fracture in the fibula **4**.

A further alternative embodiment is shown in FIGS. **26**A-**26**E. In accordance with one implementation, this device **270** can be implanted using a different method than that described above. In this embodiment, the first anchor **12** and the tether **16** are a single, unitary component **272**, as best shown in FIG. **26**A, in which the first anchor **12** is a button anchor **12**. That is, the anchor **12** and tether **16** are permanently attached in a component **272** that is comprised of a long tubular member **16** having a head **12** at the proximal end. Alternatively, the anchor **12** and tether **16** can be separate components.

In one embodiment, the tether **16** is a threaded rod **16** as shown. The tether **16** can be made of a fully or partially polymeric material. Alternatively, the tether **16** can be made entirely or at least partially of a bio-absorbable material. In a further alternative, the tether **16** can be made of any of the materials described with respect to the tether **16** depicted in FIGS. **5**A-**5**E and described above.

In use, holes are drilled through the entire width of both the tibia **2** and the fibula **4**, resulting in a hole **274** that extends through the tibia **2** and a hole **276** that extends through the fibula **4**, as best shown in FIG. **26**B. According to one embodiment, countersink holes **278**, **280** are formed near the bone surface of both holes **274**, **276** as shown, with the holes **278**,**280** being configured to receive the button anchor **12** and the second anchor **14** (as shown in FIG. **26**D). Alternatively, counterbore holes can be formed. In a further alternative, the button anchor **12** is configured to have a thin or otherwise minimal profile that allows it to be positioned on the surface of the medial aspect of the tibia **2** without the need for a countersink hole. For example, in one implementation, the button anchor **12** can have a rounded configuration that allows it to be positioned on the surface of the tibia while minimizing the protrusion caused by the anchor **12**. In one alternative embodiment, the button **12** can be made of a flexible material, thereby resulting in greater flexibility and angular rotational freedom for the overall construct. In one implementation, an anchor **14** made of flexible material allows the surgeon to tailor the system flexibility to the needs of the patient, because, for example, different patients can exhibit different levels of baseline fibula rotation. For example, in one embodiment, the button **12** can be made of silicone or any other known flexible material for use in implantable medical devices.

As best shown in FIG. **26**C, the component **272** is positioned through the holes **274**, **276** with the first anchor **12** positioned in the countersink **278** in the tibia **2**. Once the component **272** is positioned as desired, the second anchor **14** can positioned over the distal end of the tether **16** and urged along the tether **16** (perhaps using a driver tool **282** as shown in **26**D) until the anchor **14** is positioned against the fibula **4** as desired. When the second anchor **14** is in position, any portion of the tether **16** that extends beyond the second anchor **14** away from the bones can be removed. In one embodiment, the excess portion is removed using a cutter such as the cutter **180** described above. Once the excess portion is removed, the device **270** is implanted, as shown in FIG. **26**D.

Although the present invention has been described with reference to preferred embodiments, persons skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

What is claimed is:

**1**. A method of treating a syndesmosis injury, comprising:

forming a hole through a second bone and into a first bone;

inserting a deployment assembly into the hole in the second bone, the deployment assembly comprising:

(a) an outer tube having a distal end, a proximal end, an outer diameter, and an inner diameter

(b) a tether disposed within the outer tube, the tether comprising:

(i) a flexible component; and

(ii) a base component coupled to the flexible component, said base component being substantially rigid, the base component having a distal portion that is externally threaded having a base component external thread having a base component external thread major diameter, and having a proximal portion; and

(c) a first bone anchor disposed at a distal end of the outer tube, the first bone anchor having a first bone anchor external thread having a first bone anchor external thread major diameter, the first bone anchor being coupled to a distal end of the flexible component, wherein the outer tube has a torque-transmitting engagement feature cooperating with the first bone anchor;

positioning the first bone anchor in the first bone;

removing the outer tube; and

coupling a second anchor to the base component and positioning the second anchor in the second bone or in a plate connected to the second bone,

wherein the first bone anchor external thread major diameter is greater than the outer tube outer diameter at the distal end, the outer tube outer diameter is greater than the outer tube inner diameter, the outer tube inner diameter is greater than the base component external thread major diameter, and the base component proximal portion is sufficiently narrow so that the second anchor can advance non-rotatingly along the proximal portion of the base component.

2. The method of claim 1, wherein the positioning the first bone anchor further comprises rotating the deployment assembly to screw the first bone anchor into the first bone.

3. The method of claim 1, further comprising urging the second anchor distally in relation to the tether, wherein urging the second anchor distally comprises sliding the second anchor distally along the proximal portion of the base component, followed by engaging an internal thread of the second anchor with the base component external thread, followed by rotating the second anchor with respect to the base component to further advance the second anchor distally, and further comprising severing an extending portion of the base component so that a remaining portion of the base component does not protrude beyond the second anchor.

4. The method of claim 1, further comprising first positioning a guide wire through the second bone and into the first bone, wherein the forming the hole in the second bone further comprises positioning a drill over the guide wire and drilling the hole in the second bone.

5. A method of treating a syndesmosis injury, comprising:

forming a hole through a second bone and into a first bone;

inserting an implantation tool comprising a deployment assembly into said hole in said second bone, said deployment assembly comprising:

a first bone anchor, said first anchor being suitable for placement in said first bone, said first bone anchor having a first anchor external thread having a first anchor external thread major diameter, said first bone anchor having at its proximal end a coupling feature;

an outer tube having a lumen therewithin and having, at its distal end, a protrusion capable of being received in said coupling feature of said first anchor;

a tether comprising a flexible component coupled to said first bone anchor and a base component coupled to said flexible component, said base component being substantially rigid,

wherein when the outer tube is coupled with the first bone anchor said first bone anchor is disposed distally of said outer tube and said base component is contained entirely within said lumen of said outer tube and does not extend beyond a proximal end of the implantation tool;

positioning said first bone anchor in said first bone;

removing said outer tube; and

coupling a second anchor to a proximal end of said base component and positioning said second anchor in said second bone or in a plate connected to said second bone,

wherein a distal portion of the base component has an external thread and a proximal portion of the base component is unthreaded, and wherein the second anchor has an internal thread engageable with the external thread of the base component, and wherein the unthreaded portion of the base component is sufficiently long so that when the second anchor, while engaged with a driver tool having a central bore therethrough, begins to engage the external thread of the base component, some of the base component protrudes proximally from the driver tool.

6. The method of claim 5, further comprising first positioning a guide wire through said second bone and into said first bone, wherein the forming said hole in said second bone further comprises positioning a drill over said guide wire and drilling said hole in said second bone.

7. The method of claim 5, wherein the positioning said first bone anchor in said first bone further comprises rotating said deployment assembly to screw said first bone anchor into said first bone.

8. The method of claim 5, wherein positioning said first bone anchor into said first bone further comprises positioning said first bone anchor into said first bone such that said proximal end of said first bone anchor is substantially flush with a surface of said first bone.

9. The method of claim 5, further comprising, after said coupling said second anchor to said proximal end of said base component, urging said second anchor distally in relation to said tether, thereby urging said second anchor toward said first borne anchor.

10. The method of claim 9, wherein urging the second anchor distally in relation to the tether further comprises rotating the second anchor with respect to said base component.

11. The method of claim 5, wherein said flexible component comprises a suture.

12. The method of claim 5, wherein said flexible component comprises a resorbable suture.

13. The method of claim 5, wherein said flexible component has a strength such that said flexible component fails before either said first bone anchor or said second anchor is pulled from a respective implantation site.

14. The method of claim 5, wherein said outer tube does not extend radially beyond said major diameter of said external threads of said first bone anchor.

15. The method of claim 5, further comprising:

examining a radiographic image to determine an initial position of said second bone in relation to said first bone; and

adjusting the positioning of said second anchor based on said initial position of said second bone in relation to said first bone to achieve a desired position.

16. The method of claim 5, further comprising:

evaluating ankle function to determine an initial position of said second bone in relation to said first bone; and

adjusting the positioning of the second anchor based on the initial position of said second bone in relation to the first bone to achieve a desired position.

17. The method of claim 5, wherein said first bone is the tibia bone and said second bone is the fibula bone.

18. A method of treating a syndesmosis injury, comprising:

forming a hole through a second bone and into a first bone;

inserting a deployment assembly into said hole in said second bone, said deployment assembly comprising:

a first anchor, said first anchor being suitable for placement in said first bone, said first anchor being distally located;

a tether, said tether comprising a flexible component and a base component, wherein said base component is substantially rigid, wherein said first anchor is coupled to said flexible component, and said flexible component is coupled to said base component, and said base component extends more proximally than said flexible component, and wherein said base component has an external thread and a proximal portion of the base component is unthreaded;

positioning said first anchor in said first bone; and

coupling a second anchor to a proximal end of said base component, wherein said second anchor has an internal thread complementary to said base component external thread; and

positioning said second anchor in said second bone or in a plate connected to said second bone,

wherein the unthreaded portion of the base component is sufficiently long so that when the second anchor, while engaged with a driver tool having a central bore therethrough, begins to engage the external thread of the base

component, some of the base component protrudes proximally from the driver tool.

**19**. The method of claim **18**, further comprising removing an excess length from said proximal portion of said base component.

**20**. The method of claim **18**, wherein positioning said second anchor in said second bone comprises rotating said second bone anchor with respect to said base component.

**21**. The method of claim **18**, wherein said flexible component comprises a resorbable suture.

**22**. The method of claim **18**, further comprising, after said positioning said second anchor in said second bone, evaluating a relative position of said bones, and re-positioning said second anchor to achieve desired positioning of said bones.

**23**. The method of claim **18**, wherein said second anchor comprises a head having a curved underside of said head between a top of said head and a body of said second anchor, wherein said curved underside has a shape that corresponds to a shape of a hole in said plate.

**24**. A method of treating a syndesmosis injury, comprising:

forming a hole through a second bone and into a first bone;

inserting a deployment assembly into said hole in said second bone, said deployment assembly comprising:

an outer tube having an outer diameter and an inner diameter and having a lumen therewithin and having, at its distal end, a protrusion;

a first anchor located distally of said distal end of said outer tube, said first anchor being suitable for placement in said first bone, said first anchor having an external thread having a major diameter, said first anchor having a coupling feature located within said major diameter and capable of receiving said protrusion of said outer tube;

a tether comprising a flexible component coupled to said first anchor and a base component coupled to said flexible component, said base component being substantially rigid,

wherein some of said base component is more proximal than said flexible component,

wherein said base component has a base component external thread,

wherein said base component fits inside said lumen of said outer tube;

positioning said first anchor in said first bone, wherein said positioning comprises applying torque to said outer tube causing rotation and advancement in a distal direction of said first anchor;

withdrawing said outer tube in a proximal direction while said flexible component remains coupled to said first anchor and said base component remains coupled to said flexible component; and

coupling a second anchor to said base component and positioning said second anchor in said second bone or in a plate connected to said second bone, wherein said second anchor has an internal thread complementary to said base component external thread, wherein said coupling includes rotating said second anchor with respect to said base component,

wherein the first bone anchor external thread major diameter is greater than the outer tube outer diameter at the distal end, the outer tube outer diameter is greater than the outer tube inner diameter, the outer tube inner diameter is greater than the base component external thread major diameter, and the base component further comprises a proximal portion that is sufficiently narrow so that the second bone anchor can advance non-rotatingly along the proximal portion of the base component.

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